

CHAPTER

6

**Payment for pharmacy
handling costs in hospital
outpatient departments**

R E C O M M E N D A T I O N S

6A The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

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6B The Secretary should:

- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Payment for pharmacy handling costs in hospital outpatient departments

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 mandates that MedPAC report on whether the Secretary should adjust payments in the outpatient prospective payment system (PPS) for pharmacy and nuclear medicine handling costs. The issue arises because Medicare will begin to pay for certain drugs, biologicals, and radiopharmaceuticals based on acquisition costs in 2006. Previously, the payment rates for these items were higher, providing hospitals with resources to cover handling costs. The Commission concludes that handling costs are nontrivial and an adjustment is warranted. However, any adjustment should be budget neutral because when CMS established the outpatient PPS, payments were based on hospital charges that reflected these handling costs. This chapter closes with a discussion of the significant unbundling that has occurred within the outpatient PPS. The current granular approach to paying for drugs undermines incentives for efficient use of services in broader payment bundles. The Commission suggests that, in the future, CMS identify larger payment bundles.

In this chapter

- Is a payment adjustment needed?
- How should a payment adjustment be structured?
- How should handling costs be measured?
- What are the options for collecting data?
- A longer term agenda: Broader payment bundles in the outpatient PPS

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 changed the way in which Medicare will pay hospitals for certain drugs, biologicals, and radiopharmaceuticals delivered in their outpatient departments and covered under the outpatient prospective payment system (PPS). The law affects radiopharmaceuticals and products that Medicare reimbursed under the outpatient PPS's pass-through mechanism as of December 2002 (called specified covered outpatient drugs). The pass-through mechanism enables additional payment for those technologies for a period of two to three years, after which CMS incorporates them into the payment system.

Providers use many, but not all, of the drugs and biologicals on the pass-through list in cancer treatment.

Other pass-through drugs and biologicals treat rheumatoid arthritis, diseases of immune deficiency, and additional conditions. Table 6-1 lists the drugs and biologicals receiving the highest total payments under the outpatient PPS in 2002; Table 6-2 lists the top radiopharmaceuticals. In general, hospital pharmacies handle drugs and biologicals. Radiopharmaceuticals are radioactive agents used for diagnostic or therapeutic purposes. Many providers use radiopharmaceuticals in nuclear imaging procedures; others target drugs and radioisotopes in certain cancer treatments. Radiopharmaceuticals may be handled by hospital pharmacies, radiopharmacies or, more typically, nuclear medicine departments.

When these drugs, biologicals, and radiopharmaceuticals (hereafter referred to as "products") were on the pass-through list, CMS paid hospitals 95 percent of average wholesale price (AWP), a benchmark price that researchers and auditors have found to be well above acquisition cost (MedPAC 2003, GAO 2001, OIG 2001). After CMS moved these products off the pass-through list, the agency set payment rates using the general approach of the outpatient PPS: calculating the median value of hospital charges reduced to costs using adjustment factors from hospital cost report data. Manufacturers believe that these payment rates are too low (PhRMA 2002).¹

In the MMA, the Congress directed CMS to pay hospitals for specified covered outpatient drugs in different ways than before. Beginning in 2006, the MMA mandates that CMS set payment equal to average acquisition cost, taking into account data collected by the Government Accountability Office (GAO) through a survey of hospitals. GAO surveyed hospitals from fall 2004 to spring 2005. It provided CMS with data on acquisition costs in spring 2005.

The MMA also required MedPAC to determine whether the outpatient PPS should have a payment adjustment to cover services provided by hospital pharmacies or nuclear medicine departments when they handle these products. The law directed MedPAC to suggest a method for making such an adjustment, if needed. (Relevant excerpts from the MMA language requesting the study can be found at the end of this chapter, p. 152.)

MedPAC's study focuses on the handling costs that pharmacy and nuclear medicine departments incur for storing, preparing, transporting, and disposing of the products. The study excludes the acquisition costs of the products themselves, which GAO is studying. The study

TABLE 6-1 Study drugs and biologicals with highest payments in 2002, ranked highest to lowest

APC in 2002	APC title in 2002	Brand name(s)
0733	Non-ESRD epoetin alpha injection	Epogen, Procrit
0849	Rituximab	Rituxan
7043	Infliximab injection	Remicade
0863	Paclitaxel injection	Taxol
0811	Carboplatin injection	Paraplatin
0823	Docetaxel	Taxotere
0828	Gemcitabine HCL	Gemzar
0830	Irinotecan injection	Camptosar
9115	Zoledronic acid injection	Zometa
9217	Leuprolide acetate suspension	Lupron, Eligard
0730	Pamidronate disodium	Aredia
0728	Filgrastim injection	Neupogen
7049	Filgrastim injection	Neupogen
1613	Trastuzumab	Herceptin
0768	Ondansetron HCL injection	Zofran
7046	Doxorubicin HCL liposome injection	Doxil
9005	Retepase injection	Retavase
9119	Pegfilgrastim injection	Neulasta
0852	Topotecan	Hycamtin
0810	Goserelin acetate implant	Zoladex
1203	Verteporfin for injection	Visudyne
7031	Octreotide acetate injection	Sandostatatin
0855	Vinorelbine tartrate	Navelbine
9002	Tenecteplase	TNKase
0905	Immune globulin	*

Note: APC (ambulatory payment classification), ESRD (end-stage renal disease), HCL (hydrochloride).
* Various manufacturers.

Source: MedPAC analysis of 2002 outpatient claims file from CMS.

also excludes costs associated with administering the product to the patient—such as preparing the patient for chemotherapy, monitoring the patient during an infusion, or treating side effects—because Medicare pays separately for administration of chemotherapy and other drugs, as well as for nuclear medicine procedures. MedPAC’s analysis considers broader issues that this study raises, namely the design of payment rates.

In considering the question of pharmacy handling costs in hospitals, a review of the literature revealed little relevant research or data. MedPAC consulted widely with stakeholders, including numerous hospital pharmacy directors and administrators, representatives of hospital associations (including cancer hospitals), pharmaceutical distributors, representatives of product manufacturers, and CMS staff. We also coordinated our work with that of GAO. To better understand how hospital pharmacies operate, MedPAC staff conducted a site visit to a cancer center in the Washington, DC, area. We then developed a conceptual framework with assistance from a contractor, a technical advisory panel, and four facilities that agreed to serve as case studies.

Is a payment adjustment needed?

MedPAC’s analysis indicates that handling costs for these products are not insignificant. CMS built the existing outpatient PPS payment pool using hospital charges that reflected handling costs. Consequently, the Commission concludes that CMS should make a payment adjustment, but it should be budget neutral. In other words, total payments for all services would remain the same, and the resources for an adjustment would come from a redistribution of payments from other categories of services.

Background

Determining whether the outpatient PPS needs a payment adjustment requires an understanding of previous payment policies. Historically, hospitals generally charged only for the drug provided; they did not routinely develop separate charges for their pharmacy services. In a recent survey of hospital charging practices, most respondents indicated that this practice continues today (Worzala and Ashby 2004). In our discussions with hospitals, officials indicated that they set charges for drugs and radiopharmaceuticals high enough to reflect the products’ handling costs as well

**TABLE
6-2**

Study radiopharmaceuticals with highest payments in 2002, ranked highest to lowest

APC in 2002	APC title in 2002
1600	Technetium-99m sestamibi
0705	Technetium-99m tetrofosmin
1603	Thallium-201
1775	FDG
1601	Technetium-99m medronate
1622	Technetium Tc-99m mertiatide
1604	In-111 capromab pendetide
1627	Technetium-99m labeled RBCs
1348	I-131 solution
1188	I-131 capsule

Note: APC (ambulatory payment classification), FDG (fluorodeoxyglucose F18), Tc (technetium), In (indium), RBCs (red blood cells).

Source: MedPAC analysis of 2002 outpatient claims file from CMS.

as their acquisition costs. Historically, Medicare payments were sufficient to cover both.

Under the outpatient PPS, CMS generally sets payments based on hospitals’ charges, which the agency reduces to estimated costs using a cost-to-charge ratio from Medicare cost report data. Using this methodology, CMS incorporates handling costs into the payment rates because handling costs are built into hospitals’ charges. Many observers have voiced concerns about the completeness of the data available to CMS and the accuracy of this methodology when setting rates for specific items (see more detailed discussion in the section about broader payment bundles on p. 150). Nevertheless, CMS included handling costs as a component of hospital-wide expenses when it set up the outpatient PPS. Thus, the current payment system incorporates handling costs in the total payment pool.

The MMA requires GAO to collect acquisition cost data that CMS then will use to set payment rates for these products in 2006. If the acquisition cost data are not available, the MMA allows CMS to use the drug price data collected in order to pay physicians for Part B drugs—that is, average sales price or prices from competitive acquisition arrangements. Under either of these approaches, the payment for the product would no longer include handling costs.

Our conversations with stakeholders and analysis of data from Maryland hospitals and from Medicare cost reports

suggest that handling costs are not negligible. However, because most hospitals do not develop charges for pharmacy handling costs today, they do not have precise information about the magnitude of these expenses.² The fact that hospitals typically prepare inpatient and outpatient drug and biological products within the same pharmacy complicates the measurement of handling costs. In interviews that MedPAC staff conducted for this research, hospital pharmacy directors stated that the types of medications that providers administer more frequently in outpatient departments generally require more pharmacy preparation time than do those for inpatients. Although data are not available to make a comparison, the pharmacy directors believed that inpatients generally received more medications as pills, injections, or as simple intravenous (IV) solutions, while outpatients generally had a larger proportion of complex infusion therapies that pharmacists needed to reconstitute or compound. Radiopharmacists or pharmacy technicians usually prepare radiopharmaceuticals in a separate nuclear medicine department, or commercial nuclear pharmacies under contract with the hospital deliver near-ready unit doses.

One study of 1996 Medicare hospital cost report data found that labor and costs other than the acquisition cost of drugs accounted for about one-third of expenses associated with pharmacy-related cost centers—where hospitals state the costs of drugs and of operating the pharmacy department (Kathpal Technologies 1999). However, it is unclear whether available data are comparable across hospitals. The Kathpal study relied on a sample of 55 hospitals. MedPAC analyzed recent Medicare cost report data for more than 3,300 hospitals and found that hospitals are not consistent in their reporting of pharmacy costs. This inconsistency makes it difficult to separate drug acquisition costs from pharmacy handling costs. MedPAC found that in nearly 1,200 hospitals in which reporting appears to be comparable, wages, salaries, and fringe benefits make up 25 percent, on average, of pharmacy-related direct costs. The cost of purchasing pharmacy supplies and acquiring drugs and biologicals account for the remaining 75 percent of direct costs. Radiopharmaceutical handling costs are typically an expense of running a nuclear medicine department, and we were unable to estimate the relative magnitude of these costs from Medicare cost report data.

MedPAC also analyzed cost data for about 40 hospital pharmacy departments in Maryland from 2001 to 2003—nearly all the hospitals in that state (see text box).³ Those data show that pharmacy department wages and

salaries, fringe benefits, and supplies made up 26 percent to 28 percent of pharmacy departments' direct costs (defined as the cost of labor, benefits, and supplies plus the acquisition cost of drugs).

Moving to a payment system based on acquisition cost for separately paid drugs means that the system will no longer compensate hospitals for handling costs as part of the payment for the drug itself.⁴ Yet handling costs are not negligible. In addition, some hospitals provide more of these services than others (for example, hospitals that specialize in cancer care, or teaching hospitals that provide more new technology services). Therefore, the move to reimburse for these products based on acquisition cost could have redistributive effects among facilities. For the reasons mentioned above, the payment system should include an adjustment for handling products when Medicare pays for the products at acquisition cost.

A budget-neutral payment adjustment

A payment adjustment for handling costs should be budget neutral because when CMS established the outpatient PPS, it based payments on hospital charges that reflected these handling costs. A payment adjustment would ensure that Medicare reimburses hospitals for the costs of these services more directly than before, but payments should come from the redistribution of resources already within the outpatient PPS payment base.

Prospective payment systems comprise three basic parts:

- a classification system to define the services for which Medicare is paying (called ambulatory payment classification [APC] groups in the outpatient PPS);
- relative weights to determine the relative payments among services; and
- a conversion factor Medicare uses to set the level of payments.

Together with volume, these three factors determine the size of the payment pool.

MedPAC's study primarily focuses on the classification system and the relative weights. A payment adjustment may require creating new APCs, which would change the classification system. Setting appropriate payment rates for new APCs would require establishing relative weights.

Current law generally requires that changes to the classification system and relative weights be made in a budget-neutral fashion. MedPAC's study does not address

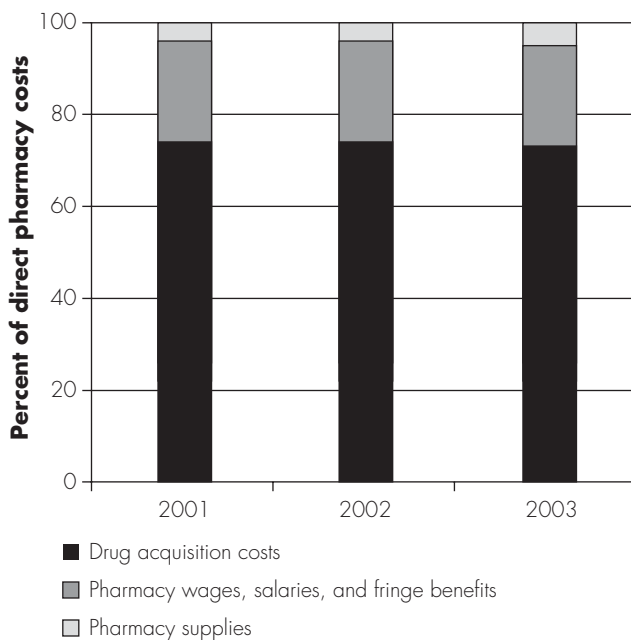
Hospital pharmacy costs in Maryland

In order to measure handling costs for drugs and radiopharmaceuticals delivered in hospital outpatient departments, MedPAC analyzed data from the Maryland Health Services Cost Review Commission (HSCRC). Maryland regulates hospitals' charges; all payers base their payments on those charges. Maryland established the HSCRC in 1971 to

set the rates that hospitals charge for the all-payer system. Due to the nature of its work, the HSCRC possesses comprehensive hospital accounting data that helped us understand the types of costs that hospitals incur for outpatient pass-through drugs. MedPAC analyzed HSCRC hospital pharmacy accounting data from approximately 40 Maryland hospitals for 2001 to 2003. The data include the following types of hospital pharmacy costs: acquisition cost of drugs, the pharmacy department's other direct costs, capital costs, payment adjustments, and an allowance for profit. We call the sum of these costs "total direct drug expenses."

FIGURE 6-1

Labor and supplies components of direct pharmacy expenses are stable



Source: MedPAC analysis of hospital cost report data from the Maryland Health Services Cost Review Commission.

MedPAC analyzed three components of direct drug expenses: (a) drug acquisition costs, (b) pharmacy wages, and (c) pharmacy supplies. In all three years, the nondrug elements of direct costs made up 26 percent to 28 percent of the total (Figure 6-1).

As these data illustrate, nondrug costs make up a nontrivial proportion of costs. Figure 6-1 also shows that the average proportions did not change much from year to year. Overall, these data demonstrate that the handling costs hospital pharmacies incur are not negligible; thus, Medicare payments should account for these costs.

Limitations of the data

Although these data can inform the relationship between cost categories within the pharmacy, they do not include information on the types or volume of drugs prepared in the pharmacy—nor do they separate the products delivered in outpatient departments from those used by inpatient departments. Finally, these data exclude radiopharmaceuticals. ■

the level of payments—this task is done through the annual updates to the conversion factor, which the Congress determines based on guidance from MedPAC.⁵

In addition to the outpatient PPS's structure, other factors support a budget-neutral payment adjustment:

- Hospital officials and others told MedPAC staff that hospitals build handling costs for drugs, biologicals,

and radiopharmaceuticals into the charges for the products themselves as part of the markup over costs. Therefore, the original payment pool that CMS based on hospital charges (reduced to costs) reflected handling costs. In recent years, relative weights derived from charges (reduced to costs) also reflect handling costs.

- In setting up pass-through payments in the Balanced Budget Refinement Act of 1999, the Congress designed the policy to be budget neutral (MedPAC 2002).⁶
- Through the MMA, the Congress legislated interim payment rates in 2004 and 2005 for the products in this study based on AWP. Because AWP are benchmark prices well above acquisition costs, that policy provided additional resources within the system to cover pharmacy handling expenses. By law, increased payments resulting from the interim payment rates were made with new money—that is, the policy was not budget neutral.⁷ Medicare has subsequently built this increased spending into the total payment pool.

How should a payment adjustment be structured?

Hospitals appear to incur nontrivial costs in handling separately paid drugs and radiopharmaceuticals. Thus, as the outpatient PPS moves toward reimbursing hospitals for drugs at their acquisition cost, it should also provide some payment for handling costs.

To cover reasonable pharmacy and nuclear medicine handling costs, a payment adjustment could take one of several forms:

- a percentage markup on acquisition costs,
- a handling fee tied to each administration to a patient, or
- inclusion of handling costs in a larger payment bundle.

Markup on acquisition costs

Medicare could link payment for handling costs to the acquisition cost of products. Indeed, some stakeholders interpret the Kathpal study’s findings (1999) as follows: A payment methodology to reimburse hospitals for pharmacy department costs should provide, on average, a 50 percent markup over the acquisition cost of products (ACCC 2004). Under that logic, if handling costs make up one-third of the sum of handling costs plus acquisition costs, Medicare would need to pay 1.5 times the acquisition cost to cover both costs.

This approach would be administratively straightforward, provided that Medicare can collect reliable data on acquisition costs. However, handling costs may not be directly proportional to a product’s acquisition costs. Prices that hospitals pay to purchase the products depend on a number of factors, such as the availability of generic or therapeutic substitutes, the volume that each hospital (or each hospital system) buys, and the abundance or scarcity of the products. Some drug therapies with lower acquisition costs have relatively high handling costs because these therapies require that a pharmacist reconstitute them over a lengthy period or prepare them for infusion using specialized safety equipment. Other products carry relatively high price tags because they are single-source drugs, but some are manufactured in a form that requires less pharmacy handling (for example, prepackaged unit doses, or liquids rather than powders).

Handling fee per administration

A second way to structure an outpatient PPS payment for handling costs is to reimburse hospital pharmacies for each preparation of a product that is administered to a patient. Unlike providing a markup over the product’s acquisition cost, a per administration handling fee could provide a more direct link between Medicare’s payment and the resources required to carry out pharmacy and nuclear medicine departments’ tasks. This approach is similar to the way in which Medicaid and private payers reimburse retail pharmacies for the dispensing costs of outpatient prescription drugs.

MedPAC staff’s discussions with hospital pharmacy directors and other stakeholders revealed wide variation in the processes and resources required to handle drug therapies in hospital outpatient departments. For example, a hospital pharmacy may require the ability to dispense not only simple pills but also highly toxic chemotherapy agents for intravenous infusion. Some patients may receive a single drug; others receive a combination therapy that requires the pharmacies to mix products before administering them. Therefore, CMS may want to classify products into broad categories, with each group requiring similar levels of pharmacy resources. The agency would then set a fixed payment to cover the handling costs for each category of drugs and radiopharmaceuticals.⁸

This classification approach is preferable to a markup over acquisition cost because it links payment more closely to actual resource use. On the other hand, it is more administratively complex. However, these complexities do

not appear to be insurmountable and should diminish over time. To institute this approach, CMS would have to create categories of handling costs, establish Healthcare Common Procedures Coding System (HCPCS) codes for them, and set payment rates. Hospitals would have to bill Medicare for their handling costs using the new HCPCS codes. Once Medicare began receiving such charges, it could set payment rates for handling costs in each category in the same manner that it does for other APCs within the outpatient PPS—by evaluating the median level of costs among submitted charges (reduced to costs). Hospitals would need advance notice of the new codes as well as time to collect appropriate cost information, develop the charges, and modify their billing operations.

Can hospitals set charges for their handling services? Although most hospitals do not currently charge for their handling costs, they set charges for many different services and should be able to develop charges for handling costs as they have done for other costs. In fact, one hospital official with whom MedPAC spoke stated that his facility had already developed charges for pharmacy services. Other hospitals indicated that if required, they could do so.⁹ Through four case studies (described on p. 147), MedPAC assessed whether hospitals could estimate their handling costs, which could provide valuable information for setting charges. The case-study facilities successfully estimated costs, although they found the process time consuming. Hospitals may need a transition period before CMS deems that the charge data submitted are reliable enough to set payment rates. CMS also would need to develop a process for evaluating the handling costs of new products and categorizing them within appropriate APCs.

Other payers also often reimburse hospitals for handling costs through payment for the product itself. If Medicare reimbursed handling costs through separate APCs, that approach could conflict with hospitals' method of obtaining payment from other payers. However, it seems likely that once Medicare begins paying for these products based on acquisition costs, other payers would want to follow suit. Under that scenario, developing standard charges would help hospitals ensure more direct payment for handling costs from all payers.

Larger payment bundles

Alternatively, CMS could create larger bundles of services within the outpatient PPS that include pharmacy and nuclear medicine handling costs. In order to ensure that

Medicare reimburses hospitals for handling costs, hospitals would still need to develop charges for pharmacy services. CMS would reimburse hospitals for bundles that include not only the acquisition cost of clinically similar products but also their handling costs. This approach is consistent with the original intent behind the outpatient PPS—to provide a predetermined level of payment for clinically similar services (APCs), thereby giving hospitals an incentive to control costs (MedPAC 2000).

Over time, CMS has expanded the number of APCs, narrowing certain bundles of services, to the point of providing separate payment for many individual products. The Congress required CMS to set up separate payments for the products covered in MedPAC's study because these products are newer technologies that generally have higher costs than other therapies. Proponents were concerned that if these products were bundled within broader APCs that also included less costly therapies, reimbursement would be too low for hospitals that chose to provide newer products. Broad bundles, proponents believe, could adversely affect patient care if newer therapies represent significant advances in treatment that are disadvantaged by the design of APCs.

Yet arguably, in cases where older and newer agents are therapeutically equivalent, it is appropriate for CMS to include both older and newer agents within the same APC. This approach would give hospitals a greater incentive to decide whether the clinical outcomes of newer therapies justify their higher acquisition costs. Moreover, not all new products constitute significant advances in therapy.

How should handling costs be measured?

Measuring handling costs is primarily a cost accounting exercise. However, after a literature review and conversations with stakeholders, MedPAC concluded that no systematic, consensus-based approach exists for identifying or measuring handling costs for these products. To break down the process of measuring handling costs, we took three steps:

- Developed a framework to identify and define the handling costs.
- Classified the study products into categories according to characteristics related to the level of resources used

in handling, including radioactivity, toxicity, mode of administration, and special-handling considerations.

- Conducted case studies in four facilities to test the validity of the framework and classification system, as well as to assess hospitals' ability to estimate the relative handling costs across categories by resource use.

Framework

In order to measure handling costs, one must first define them. With the help of a contractor, MedPAC developed a framework that lays out the categories of costs (Figure 6-2). The framework and definitions are sufficiently broad to span the range of products covered by this study and to apply to both pharmacy and nuclear medicine departments. MedPAC asked a technical advisory panel of experts in pharmacy, nuclear medicine, hospital finance, and cost accounting to evaluate the framework. We then modified the groupings based on the panel's input. (A list of the members of the advisory group is available from MedPAC upon request.) The dimensions of handling costs that MedPAC considered include:

- pharmacy or nuclear medicine management, including regulatory compliance;
- storage, including inventory management;

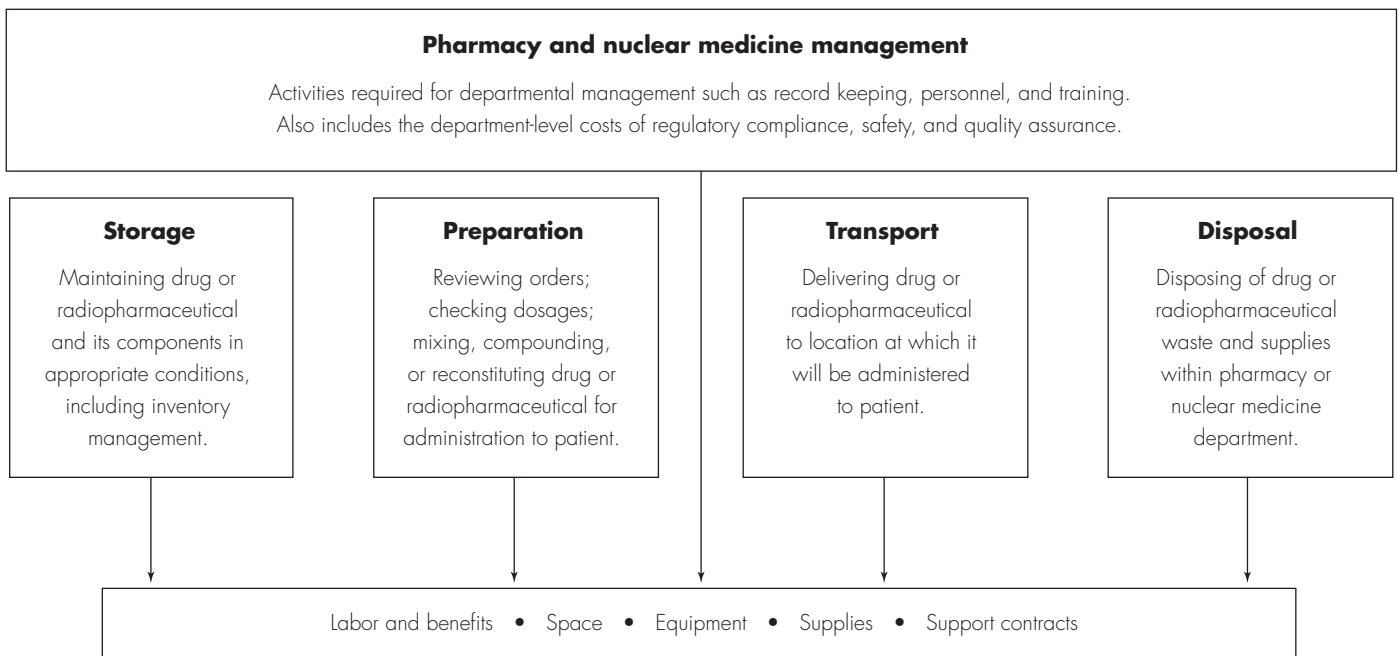
- preparation, including review of drug orders and dosage calculations;
- transport within the hospital (such as from the pharmacy to the infusion suite); and
- disposal of products from the pharmacy or nuclear medicine department.

Costs for specific products will vary across these categories. Some products may have significant storage requirements (such as extremely low temperatures to maintain product integrity or shielded containers to protect workers from contamination); others may have extensive preparation costs (such as lengthy reconstitution times or complex dosage calculations and verifications). In some cases, management of inventory for high-cost products can be a significant expense. In concept, all handling costs should fit into at least one of the categories. Within each category, the kinds of costs to measure include:

- labor and benefits,
- space,
- equipment and supplies, and
- support contracts for other organizations to provide certain services (such as waste disposal contracts).

FIGURE 6-2

Pharmacy and nuclear medicine functions and handling costs covered by this study



Activities such as regulatory compliance and quality improvement can affect the costs in these categories. For example, studies have shown that individuals preparing toxic agents can be exposed to these agents through their skin or through breathing aerosolized particles (Morris 2005). Consequently, the National Institute for Occupational Safety and Health (NIOSH) has issued guidelines to protect workers who come in contact with antineoplastics and other drugs (NIOSH 2004). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) assesses hospitals' compliance with quality and safety standards that include guidelines for preparing products in hospital pharmacies. Accrediting bodies such as JCAHO and some state pharmacy boards have also adopted recent revisions to sterile compounding standards issued in Chapter 797 of the U.S. Pharmacopeia (USP) (U.S. Pharmacopeial Convention, Inc. 2004). In addition, many hospitals institute their own quality safeguards, such as multiple reviews of orders, to prevent medication errors. The Nuclear Regulatory Commission (NRC) and individual states regulate and license institutions that use radioactive materials. All hospitals must follow stringent NRC and state guidelines on how those materials are stored, transported, and disposed of (CORAR 2004). All of these activities should be reflected in cost elements such as the storage space required, the supplies and equipment used, or the labor involved. The costs that hospitals incur to manage and document their compliance with NRC and state guidelines fall under pharmacy and nuclear medicine management.

Categorizing products

Users of any payment adjustment for handling costs will need to group products according to the level of resources used. The study products vary considerably, from radioactive injections and chemotherapy infusions to simple oral tablets. In discussions with stakeholders and the technical advisory panel, MedPAC identified four characteristics that correlate with the level of resources needed for handling: (1) radioactivity, (2) toxicity, (3) mode of administration, and (4) special handling needs. Initially, the pharmacists in MedPAC's advisory group used these characteristics to group the study products into nine categories. After reviewing information collected by the contractor from the case studies, panel members reduced the number of categories to seven in order to collapse those with similar handling costs (Table 6-3 and the glossary of terms, p. 146). The technical advisory panel ranked categories, with

**TABLE
6-3**

Categories for drugs, biologicals, and radiopharmaceuticals and their relative handling costs

Category	Description	Relative handling cost*
1	Orals (oral tablets, capsules, solutions)	0.36
2	Injection/sterile preparations	1.00
3	Single IV solution/sterile preparations (drawing up a drug for administration)	1.28
4	Single IV solution/sterile preparations (adding a drug or drugs to a sterile IV solution) or controlled substances	1.61
5	Compounded/reconstituted IV preparations (requiring calculations performed correctly and then compounded correctly)	2.70
6	Specialty IV or agents requiring special handling in order to preserve their therapeutic value or oral cytotoxic agents (chemotherapeutic, teratogenic, or toxic) requiring personal protective equipment	5.33
7+	Cytotoxic agents (chemotherapeutic, teratogenic, or toxic) in all formulations except oral requiring personal protective equipment	N/A
7+	Radiopharmaceuticals: basic and complex diagnostic agents (including PET), therapeutic agents, and radioimmunoconjugates	N/A

Note: IV (intravenous), PET (positron emission tomography), N/A (not available). Due to insufficient cost data and handling information on radiopharmaceuticals from case-study sites, the expert panel did not provide final recommendations for categorizing these products.

*Relative handling costs are calculated as follows: MedPAC's expert panel selected at least one product from each category—generally those with the largest volume within 2002 Medicare claims under the outpatient prospective payment system. The Lewin Group calculated median handling costs for each drug selected across four case-study facilities that conducted microcosting exercises, where the median is the average of the middle two observations ranked by cost. Lewin divided each category's median cost by the median cost for Category 2. For categories in which cost information was available for more than one product, the values reflect relative costs weighted by volume.

Source: The Lewin Group for MedPAC, 2005.

radiopharmaceuticals requiring the greatest resources and oral preparations requiring the least.

In general, radioactive materials require greater handling resources than drugs. First, their additional safety requirements affect every component of handling costs. These measures include, for example, lead-lined storage, special protection during preparation, and disposal in accordance with strict regulations. Next, because the level of radioactivity changes over time according to the product's half-life, radiopharmacies need to make

Glossary of terms

Drugs: Any chemical compound used in the prevention, diagnosis, treatment, or cure of disease, for the relief of pain, or to control or improve any physiological or pathological disorder.

Biologicals: Products derived from living material—human, plant, animal, or microorganism—applicable to the prevention, treatment, or cure of diseases or injuries.

Cytotoxic agents: Substances that have toxic effects on certain cells. They are capable of causing injury or death if handled without proper personal protective equipment or if used inappropriately.

Teratogenic agents: Substances that can cause developmental malformations if handled without proper protection or if used inappropriately.

Radiopharmaceuticals: A drug or biological product that contains a radioactive entity. They are used in medicine for diagnostic and therapeutic purposes.

Diagnostic radiopharmaceuticals: Radioactive drugs or biological products that contain a radionuclide that typically is used with planar imaging, single photon emission computed tomography, positron emission tomography (PET), or other radiation detection probes.

Therapeutic radiopharmaceuticals: Agents intended to exert a cytotoxic effect on certain targeted tissues.

Radioimmunoconjugates: Agents that contain combinations of diagnostic or therapeutic substances linked with specific immune substances such as immunoglobulins, monoclonal antibodies, or antigens. They are used for specific targeting of drugs and radioisotopes in treating certain cancers. ■

additional checks and coordinate with providers and patients to ensure a therapeutic dose and to minimize wastage. These requirements, in turn, lead to management costs as hospitals must ensure and document compliance.

Toxic products, such as chemotherapy drugs, generally require greater handling costs than nontoxic drugs because of the need to protect both pharmacy workers and patients. Pharmacists must carefully check dosages and sometimes lab results to ensure that patients can tolerate the drugs. Pharmacists and technicians must prepare certain products under laminar flow hoods and use personal protective equipment. Disposal of toxic waste can be a considerable expense, and some toxic products require special storage considerations, such as extremely low temperatures. These costs accrue regardless of how the drug is administered.

The mode of administration can also influence handling costs due to the time pharmacists and technicians spend in preparing the materials. In general, stakeholders and technical advisory group members said that IV preparations require more resources than simple injections. For example, pharmacists or technicians might combine multiple drugs into a single infusion. They also may reconstitute powders into liquid form, a practice that

can require significant amounts of time. By contrast, injections generally require that the pharmacist or technician draw a measured dose into a syringe. Oral drugs generally require the fewest resources for handling.¹⁰

Special handling means some products require particular care in their preparation, storage, and transport in order to retain their therapeutic value. For example, some products should not be transferred from the hospital pharmacy to the point of administration through pneumatic tubes because they can become denatured if shaken too vigorously. MedPAC's panel of experts believed that this need for special handling was associated with greater handling costs, even if the product itself was not radioactive or highly toxic. A significant number of new agents under development are protein-based antibodies that may require special handling.

Understanding the handling costs associated with radiopharmaceuticals requires additional study because hospitals procure these products in two distinct ways: (1) either already prepared, or (2) as inputs to be prepared on site.¹¹ Handling costs vary according to the form in which hospitals order the product. This form may depend

on factors that are specific to the patient's plan of care and the product's availability. One recent survey suggests that 80 percent of hospital-based nuclear medicine facilities purchase their radiopharmaceuticals as commercially prepared patient doses from radiopharmacies (Merlino 2004). In these cases, the invoice for the product combines handling costs with acquisition costs and delivery fees. Some hospitals create their own radiopharmaceuticals on site in their nuclear medicine departments. In this case, the handling costs will be much higher but the acquisition costs will be much lower, because the hospitals purchase only component ingredients. Hospitals that prepare radioactive materials on site may have less wastage but significantly higher costs for shielding and equipment. The "make versus buy" decisions of nuclear medicine departments constitute a dimension of complexity that CMS will need to consider. Given its limited case-study approach, MedPAC could not adequately determine the relative costliness of one approach versus the other, or the circumstances in which compounding radiopharmaceuticals in house would be more appropriate.

The technical advisory panel initially discussed at least two categories for radiopharmaceutical handling costs. These two categories are based on whether products are basic diagnostic agents or one of three other types: (1) complex diagnostic agents, (2) therapeutic agents, or (3) radioimmunoconjugates. These three types of products likely have higher handling costs because they require personnel with more specialized training to prepare them, more shielding and protective equipment, and additional regulatory compliance programs (Callahan 2005). If a facility conducts its own compounding, handling costs could also include shielded storage areas for radioactive generators, additional equipment for measuring radionuclidic purity, and other supplies. Although MedPAC presents radiopharmaceuticals as one category in Table 6-3 (p. 145), the topic deserves further study to better understand how handling costs for these products differ. Based on interviews with radiopharmacists, the range of handling costs within a single category of radiopharmaceuticals can be greater than the range within any of the other product categories. Thus, CMS may want to consider establishing multiple categories for radiopharmaceuticals.

Case studies

In order to validate the proposed framework and classification of products, MedPAC contracted with

The Lewin Group to conduct four case studies of hospital outpatient pharmacy and nuclear medicine department handling costs. A case-study approach helped to ensure that we employ common definitions and have a more thorough understanding of participating facilities' handling costs.¹² Lewin asked each hospital or hospital system to categorize the study products using the proposed classification system to determine whether the facility put products into the same categories as the pharmacists on our advisory panel. Lewin also asked the case-study sites to estimate handling costs for at least one product in each category, using the proposed framework to identify handling costs.

MedPAC does not claim that one can generalize from estimates of handling costs provided by four case-study facilities to all hospitals. Consequently, MedPAC asked Lewin to report on relative costs across categories of products rather than reveal specific dollar-value estimates. This confidential approach not only helped secure hospitals' participation but also allowed for comparison of relative costs across hospitals without having the results confounded by the level of costs.¹³

To check the reliability of the classification developed by the pharmacists on the technical advisory panel, the contractor asked each case-study facility to put about 230 products covered by this study into one of nine initial categories.¹⁴ By comparing responses across facilities, Lewin could then assess whether the categories were clear and well-understood and whether different pharmacists put drugs into the same categories (a reliability test). The contractor asked case-study facilities if the categories correlate well with the resources they devote to pharmacy handling costs. Preliminary responses from those interviews suggested that most of the categories were clear, with pharmacists placing 83 percent of the products into the same categories.¹⁵ After reviewing case-study results, the advisory panel reassigned a small number of products to other categories, which raised the rate of correspondence to 89 percent. Both the advisory panel and participating sites reported that the categories were consistent and reflected increasing levels of handling costs. One caveat to this analysis, however, is that only one of the case-study hospitals compounds its own radiopharmaceuticals.

Four facilities undertook microcosting analyses of handling costs for unit doses of six to nine products, one from each category that they could cost (three facilities could not cost radiopharmaceutical products because they

contract out nuclear medicine services). The four facilities' cost analyses followed MedPAC's framework for defining handling costs. The result was a detailed costing of the functions shown in Figure 6-2 (p. 144): pharmacy and nuclear medicine management, storage, preparation, transport, and disposal. The pharmacists in the advisory group selected specific products in each category that generally reflect the highest volume products typifying the categories' characteristics. Lewin asked all of the facilities to cost out the same product for seven categories; in two categories, one hospital costed a different product because it did not use the product selected by the advisory group.

Facilities reported that the costing exercise was feasible and that they could isolate the inputs of handling costs. However, they also reported that the exercise was time consuming, requiring between 16 and 40 hours to complete. In addition, the contractor made follow-up phone calls with case-study facilities to ensure that the components of cost were comparable to one another. Nevertheless, the exercise showed that it is possible for hospitals to measure handling costs as they do routinely for other services. This exercise would allow hospitals to develop charges for pharmacy services.

The results of the microcosting exercise show that handling costs generally increase across the categories (Table 6-3, p. 145). The expert panel arrived at these seven categories after reviewing results of the microcosting exercise using nine categories and then collapsing them.¹⁶ To calculate the relative values, Lewin first took the median of estimated costs for each category across case-study sites.¹⁷ Then, Lewin divided each category's median cost by the median for Category 2, injections/sterile preparations. Thus, the median handling costs for Category 3, simple IV solutions/sterile preparations (where a single drug is added to an IV) or controlled substances, are about 1.3 times those for Category 2. The costs for Category 4, complex IV solutions in which the pharmacist must perform calculations correctly to compound the preparation, are 1.6 times those of Category 2. Similarly, Category 6, cytotoxic agents in all formulations except oral, which require the pharmacist or technician to use personal protective equipment, have handling costs that are approximately 5.3 times those of Category 2. Note that since Lewin could not collect sufficient information about the handling costs of radiopharmaceuticals, these products were presented as one category and without a

relative value. However, the data that Lewin was able to collect suggest that these handling costs could vary widely and relative values are likely to be considerably higher than those shown for Categories 1 through 6. For this reason, radiopharmaceuticals may require several categories of handling costs.

Of course, uncertainty exists behind each set of cost estimates from the case studies. For example, analysts at one facility initially estimated labor costs assuming that pharmacists and pharmacy technicians "multitask"—that is, work to prepare several products at the same time. Because the other case-study sites did not use a similar approach, the contractor asked that facility to reestimate labor costs without its multitasking assumption. If multitasking is common when handling these products, the level of "true" handling costs would be lower than those collected for this study, although relative costs might not be affected.

Other costs are likely understated. For example, many hospitals are only in the initial phases of carrying out new regulatory guidelines, such as USP's Chapter 797, Standards on Compounding Sterile Preparations. Compliance with those standards would likely raise estimates of handling costs for some categories of products. However, full compliance will take time, because some hospitals will need to make capital expenditures that hospital administrators may not have already built into their plans.

Given resource constraints, Lewin generally asked case-study sites to provide information for the handling costs of just a single product in each category. Clearly, however, many products would fall within each category. Although variation undoubtedly exists in handling costs among the products that fall within a given category, MedPAC relied on the expert judgment of its technical advisory panel and the informed opinions of pharmacists and finance officials at case-study sites to devise categories of products that reasonably capture gradations of resource use.

The case-study analysis demonstrates that it is feasible for hospitals to collect data that would help them establish charges for handling services.

RECOMMENDATION 6A

The Secretary should establish separate, budget-neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals.

RATIONALE 6A

When CMS begins to pay hospitals for drugs, biologicals, and radiopharmaceuticals based on their acquisition costs, the payment system will no longer directly reimburse hospitals for their costs in storing, preparing, and disposing of these products. Pharmacy handling costs are a nontrivial expense for hospital outpatient departments and thus, a payment adjustment seems appropriate. Since CMS previously built handling costs into the outpatient PPS payment pool (by basing payment on hospital charges), any adjustment should be budget neutral.

IMPLICATIONS 6A

Spending

- Given budget-neutral implementation, this recommendation will have no impact on program spending.

Beneficiary and provider

- In general, any effects on beneficiaries and providers are likely to be small. This recommendation may help ensure beneficiary access to care by more directly linking payment to handling costs. Hospitals may receive higher or lower payments based on the mix of drugs they use, but such distributional impacts are likely to be minimal.

What are the options for collecting data?

To implement a payment adjustment for handling costs, CMS would need data to set payment rates. MedPAC considered three means of collecting data: (1) surveying hospitals periodically, (2) conducting a series of microcosting analyses, and (3) requiring hospitals to submit charges. Each approach has limitations, but requiring hospitals to submit charges has the advantage of providing data in the same form that CMS uses to set payment rates for all other services under the outpatient PPS.

One approach to collecting data for setting payment rates is to survey hospitals in much the same way that the MMA directed GAO to survey hospitals on the acquisition cost of specified covered outpatient drugs, and then set payment rates based on periodic survey results. However, a survey approach might be less successful for collecting data on pharmacy handling costs than for product acquisition costs. In the case of the latter, GAO asked hospitals to provide data from product invoices—a

relatively unambiguous if tedious task for the more than 1,000 national drug codes involved. For handling costs, each hospital might use its own definitions and accounting approach for enumerating the costs of pharmacy and nuclear medicine departments, then allocate those costs across other cost centers. Previous MedPAC work on hospital charging practices suggests that these different accounting approaches would confound attempts to collect data on handling costs through surveys.

Alternatively, CMS could periodically conduct a series of microcosting analyses, in much the same way that MedPAC's case-study facilities did. However, CMS would need a larger sample of hospitals estimating costs for more products in order to develop a more representative and stable set of cost estimates. CMS could use those analyses to establish payment rates in certain benchmark years, with indexes of cost growth used to update costs in other years. For example, one recent study of pharmacy costs for preparing chemotherapy infusions used a microcosting approach (Pharmacotherapy Outcomes Research Center 2005).¹⁸ Time-and-motion studies are a common part of such exercises, in which cost analysts measure directly the amount of pharmacist and pharmacy technician time and other resources that pharmacies use to prepare specific products. Although this approach offers the most promise for measuring resource use accurately, CMS would likely find it prohibitively expensive to conduct such studies for a representative sample of hospitals and for a wide variety of drug, biological, and radiopharmaceutical products.

Under a third approach, CMS would require hospitals to submit charges for pharmacy handling costs under a limited number of separately paid APCs. Those APCs would be designed to reflect categories of pharmacy handling costs in much the same way as the seven categories of products devised by MedPAC's technical advisory panel. Hospitals would submit charges based on their handling costs for each administration delivered to a patient. If CMS needs to set payment rates before they begin to collect hospital charge data, the agency could conduct a limited number of microcosting analyses for a set of products to set initial payments. Ultimately, however, CMS would set payments in the same manner as for other APCs: by calculating the median of hospitals' charges reduced to costs for those services, thereby limiting the burden on CMS.

Requiring hospitals to set charges for handling costs has disadvantages and advantages. CMS has no control over

the level of sophistication that hospitals would use to develop charges for handling costs. While some hospitals might conduct “time and motion” studies or detailed cost analyses, other hospitals might use cruder approaches. Nevertheless, CMS would use the charges that hospitals developed from both more and less sophisticated methods to set payment rates. An advantage of requiring hospitals to set charges is that this process automatically would provide CMS with updated information about handling costs. In comparison, CMS would need to repeat surveys or microcosting analyses periodically in order to keep information current.

RECOMMENDATION 6B

The Secretary should:

- **define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;**
- **instruct hospitals to submit charges for those APCs; and**
- **base payment rates for the handling fee APCs on submitted charges, reduced to costs.**

RATIONALE 6B

In order to set more accurate payment rates for pharmacy department services, CMS should base handling fees on handling costs for preparing a drug administration or nuclear medicine procedure, rather than making these handling fees proportional to the acquisition cost of the product. CMS could use MedPAC’s framework to develop separate payments for hospital pharmacy handling costs. Our contractor conducted categorization and microcosting exercises at four case-study sites to test whether hospitals could understand the framework and collect information about handling costs in order to set charges for handling services provided by pharmacy and nuclear medicine departments. MedPAC’s analysis suggests that developing charges for handling costs is feasible.

IMPLICATIONS 6B

Spending

- This recommendation will have no impact on program spending.

Beneficiary and provider

- In general, any effects on beneficiaries and providers are likely to be small. This recommendation may help ensure beneficiary access to care by making more

direct payment for handling costs. Some hospitals may incur costs to develop charges for handling costs; however, those costs are likely to be relatively small compared with similar efforts that hospitals undertake to develop charges for all other services that they provide. For hospitals that deliver a larger volume of this study’s products, developing charges for handling costs could be worthwhile because under this recommendation, Medicare would pay hospitals directly for pharmacy department services.

A longer term agenda: Broader payment bundles in the outpatient PPS

MedPAC’s study question falls within the context of the Congress’s changes to payment rates beginning in 2006, when Medicare will pay hospitals based on the hospitals’ average acquisition costs for the study products. Therefore, our analysis focused on the need for—and design of—a payment adjustment for handling costs. However, for the longer term, a broader question is whether the current approach to paying for drugs in the outpatient PPS provides incentives for delivering those hospital services efficiently.

Under the outpatient PPS, the unit of payment is the ambulatory payment classification, or APC. The breadth or narrowness of a bundle within the outpatient PPS varies tremendously by APC. For some services, such as outpatient surgery, considerable packaging takes place. The APC includes all costs incurred by the hospital to admit and prepare the patient, staff and equip the operating room, supply products needed during the procedure (including inexpensive drugs), and observe the patient after the procedure. (Medicare pays for physician services separately.) In contrast, the outpatient PPS includes separate APCs for every drug that costs at least \$50 per administration, as well as separate payments for drug administration, and—if CMS adopts MedPAC’s recommendation—a separate handling fee.

If CMS adopts a handling fee, the outpatient PPS will have a greater degree of unbundling for drugs than other Part B payment systems. In physician offices, Medicare makes one payment for the drug, while handling costs are built into the payment for drug administration. For dialysis facilities, Medicare bundles payment for many of the drugs, their handling, and administration costs into the composite rate for dialysis services.

One can see the disproportionate unbundling of drugs in the number of APCs. All clinic visits, procedures, and diagnostic tests paid for under the outpatient PPS are described by about 450 APCs. In comparison, some 300 APCs exist for separately paid drugs, which account for a small share of payment.¹⁹

Initially, CMS proposed packaging many drugs with related procedures. It determined payments using the same process as for other items: charges from the claims reduced to costs using cost-to-charge ratios (CCRs) from cost reports. Manufacturers' concerns about the accuracy of hospital coding and methods that CMS used to set payment rates led to gradual unbundling of payments for drugs and radiopharmaceuticals as well as to the use of alternative data sources for setting payment rates.

Manufacturers and others worry that bundling would make hospitals less willing to supply expensive drugs if CMS calculated the payment rates as the median costs among claims that included lower cost products as well. They argue that newer agents provide significant advances in therapy, and thus the design of payment bundles could adversely affect patient care. Manufacturers and others also argue that the standard approach to setting payments is inadequate for expensive drugs, due to the poor quality of coding for claims and to practices that underestimate costs for more expensive items and overestimate costs for less expensive ones.

Historically, hospitals did not need to code individual drugs using HCPCS codes, nor did they need to accurately record the number of units because payment was based on total charges. Today, however, hospitals must bill separately paid drugs with a HCPCS code and must ensure that the units are accurate in order for CMS to set reasonably accurate payment rates. As experience with the outpatient PPS builds, hospitals' coding should become more accurate. But the payment system is complex, and some hospitals use antiquated billing systems. For these reasons, hospitals continue to struggle with their coding.

Charge compression results from the interaction of hospitals' methods of setting charges and CMS's method of converting those charges to costs. Generally, CMS uses a single CCR to convert the charges for all services in a single revenue center, such as pharmacy, into costs. Within a revenue center, however, some hospitals mark up inexpensive products more than they do expensive products, which leads to charge compression. For example, when setting charges for a generic antibiotic, a hospital may mark up its acquisition cost by a factor

of six, while it marks up an expensive chemotherapy drug by a factor of two. If CMS uses a single CCR that covers all pharmaceuticals to estimate costs from the resulting charges, the approach will tend to overestimate the costs of inexpensive items while generally underestimating the costs of expensive items. MedPAC's survey of hospital charge-setting practices confirmed that hospitals often use smaller markups on more expensive items. Other researchers have found similar results (GAO 2004).

Although this phenomenon may lead to inaccurate estimates of costs for individual products, the global estimate of costs for pharmacy products should not change: Any overestimate of lower cost items should generally balance out any underestimate of higher cost items. This balancing out may be one reason why concern over charge compression is greater among manufacturers of drugs, biologicals, and medical devices than among hospitals.

When some items are bundled and others are not, the payment system provides an incentive to use those products paid separately, if they are more profitable than the bundled items. MedPAC has documented considerable problems in payment for dialysis treatment—such as rapid increases in use of separately paid items—when CMS bundles payment for some services and bills separately for other services, notably drugs. CMS is conducting a demonstration to broaden the dialysis bundle and counter those problems. In the outpatient PPS, providers have an incentive to substitute a high-cost drug that is separately payable for a lower cost drug that would be bundled into the APC payment for the service. If hospitals act on this incentive, it could raise beneficiaries' overall cost sharing, Part B premiums, and Medicare's program spending.

In addition, setting payment rates for small bundles is likely to be less accurate than setting rates for larger bundles. Isolating a single input requires great precision in setting payment rates. Given the tools available to CMS, that precision may not be possible. Relying on outside data sources, such as the GAO study of acquisition costs, is administratively cumbersome. It also requires considerable administrative resources that CMS might better spend elsewhere.

With broader payment bundles, variations in charging practices across inputs are more likely to balance out, leading to payment rates that, on average, are close to costs. Furthermore, greater bundling of hospital outpatient department services could work in tandem with payment approaches that take into account quality and efficiency.

For example, rather than paying for each administration of chemotherapy, CMS may be able to identify episodes of chemotherapy treatment. Ideally, both payment and performance measurement would span entire episodes. Currently, broader bundles do not exist, but additional

research could result in a more streamlined payment system that offers better incentives. As MedPAC continues to pursue its agenda on refinements to the outpatient PPS, we will investigate this topic. ■

Mandate for this study (excerpts from Section 621 of the MMA)

Sec. 621. Hospital outpatient department (HOPD) payment reform.

(a) Payment for Drugs.

(1) Special rules for certain drugs and biologicals. Section 1833(t) (42 U.S.C. 13951(t)), as amended by section 411(b), is amended by inserting after paragraph (13) the following new paragraphs:

“(14) Drug APC payment rates.

...

“(B) Specified covered outpatient drug defined.

“(i) In general. In this paragraph, the term ‘specified covered outpatient drug’ means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

“(I) a radiopharmaceutical; or

“(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

“(ii) Exception. Such term does not include—

“(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

“(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

...

“(E) Adjustment in payment rates for overhead costs.

“(i) MedPAC report on drug APC design. The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

“(I) a description and analysis of the data available with regard to such expenses;

“(II) a recommendation as to whether such a payment adjustment should be made; and

“(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

“(ii) ADJUSTMENT AUTHORIZED. The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i). ■

Endnotes

- 1 Specifically, manufacturers believe that hospitals set their charges for higher cost drugs with smaller markups than for lower cost drugs and services. Manufacturers are concerned that if hospitals adjust drug charges to costs using a single department-wide cost-to-charge ratio, estimated costs will be too low for high-cost drugs and too high for lower cost items (PhRMA 2003). See the section on broader payment bundles later in this chapter for a more detailed discussion.
- 2 Some of the few available sources are annual national surveys of pharmacy practices in hospital settings conducted by the American Society of Health-System Pharmacists (ASHP). Although these surveys provide useful insights, they focus on the role of pharmacists in managing the medication-use process rather than tracking the cost of all resources needed to perform pharmacy services. The ASHP also conducts an annual pharmacy staffing survey to gauge the supply of and demand for pharmacists and pharmacy technicians.
- 3 Maryland uses a regulatory process to set the rates that hospitals charge. Because of its regulatory approach, the state collects detailed cost information from hospitals, including the acquisition cost of drugs, salaries and fringe benefits, and other supplies used in hospital pharmacy departments.
- 4 Given budget-neutral recalibration of the relative weights, any decrease in the relative weights for drugs, biologicals, and radiopharmaceuticals that results from moving to acquisition cost would result in slightly increased relative weights for other services. Total payments for all services would remain the same.
- 5 The outpatient PPS experienced a full market basket update in 2001, 2003, 2004, and 2005.
- 6 Despite the law, pass-through payments from August 2001 through April 2002 were not adjusted to ensure budget neutrality.
- 7 The interim payment rates depend on the type of drug and are based on AWP as of May 1, 2003. Sole-source drugs were paid between 88 percent and 95 percent of the reference AWP in 2004 and are paid between 83 percent and 95 percent of the reference AWP in 2005. Innovator multiple-source drugs are paid up to 68 percent of the reference AWP. Noninnovator multiple source drugs are paid up to 46 percent of the reference AWP.
- 8 CMS would need to consider how to pay hospitals for handling combination therapies. Options include paying a handling fee for each individual product, paying one handling fee for the more resource-intensive product of the combination, or paying one handling fee for the first product listed when they are billed for concurrent handling and a smaller percentage for each subsequent product.
- 9 Although most hospitals do not set separate charges for their handling costs, a small number do. Some hospitals also bill separately under evaluation and management codes for the time that pharmacists spend educating individual patients about their drug regimens and answering their questions.
- 10 Controlled substances constitute an exception.
- 11 Some hospitals make decisions daily about whether to prepare radiopharmaceuticals in house or to purchase commercially prepared unit doses, depending on the hospital's expected caseload of patients.
- 12 MedPAC initially considered conducting a representative survey (as GAO is doing for its study on acquisition costs) but concluded that it would be difficult to ensure the comparability of any data collected. We based that decision on the lack of common definitions for these costs and on observations from hospital pharmacy and finance directors that hospitals account for their pharmacy costs in very different ways.
- 13 Four hospitals or hospital systems committed to participating in both parts of the case-study analysis (categorizing drugs and providing estimates of handling costs). All four hospitals or hospital systems are located on the East Coast and range in size from 100 to more than 700 beds. Three are located in large urban areas (population greater than one million), and one is located in a smaller urban area. One of the facilities is an outpatient cancer center associated with a major teaching hospital. For each case study, directors of finance, pharmacists, and cost analysts generously shared their time and expertise. Two additional hospital systems—one in the South and another in the East—agreed to conduct the categorization but not the costing exercise.
- 14 Lewin did not require hospitals to categorize products that they do not dispense.
- 15 The majority of cases in which categorizations differed involved situations in which hospitals used different forms of the same product—for example, a prepackaged liquid versus a powder form that requires reconstituting.

- 16 This study's technical advisory panel initially used separate categories for oral cytotoxic agents and specialty IV agents that require special handling, but then they later grouped both within Category 5 because both agents' handling costs were of a similar magnitude. One external reviewer of this study suggested splitting those two types of agents because they believe that changes in therapy, handling procedures, and the need to track utilization warrant separate groupings.
- 17 Because there was an even number of sites (four), the median was calculated as the simple average of the two middle values. Although there was substantial variation in estimated costs for any one product across case-study sites, the cost data demonstrate that the categories reflected increasing levels of handling costs.
- 18 This study evaluated handling costs at two academic medical outpatient infusion centers and two community cancer centers. The study focused on facilities that provide only chemotherapy, rather than a mixture of medication therapies as most U.S. hospitals provide.
- 19 Given the changing definitions, it is difficult to compare the number of APCs to the share of spending. However, pass-through drugs, separately paid drugs, and blood products accounted for about 7 percent of spending in 2002.

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