

Physician-
Administered Drugs:
Distribution and
Payment Issues in
the Private Sector

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Distribution and Payment Issues in the Private Sector**

Submitted to the Medicare Payment Advisory Commission

by

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and

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Executive Summary

In 2001, Medicare expenditures for outpatient drugs were approximately \$6.4 billion and rising at a rate of 20 percent per year over the prior three years. Other research has suggested that Medicare often pays physicians at rates significantly higher than their actual acquisition costs. This report characterizes how physician-administered drugs are distributed and paid for in the private market.

We conducted 16 structured interviews with key stakeholders and others knowledgeable about the ways in which physician-administered drugs are purchased, distributed, and paid for in the private market. Respondents included oncologists, private health plans, pharmacy benefit managers (PBMs), specialty pharmacy companies, wholesalers, group purchasing organizations (GPOs), and consultants.

Traditionally, physicians have acquired physician-administered drugs for their offices through four main channels – manufacturers, wholesalers, GPOs, and local pharmacies. These methods continue to account for the bulk of purchases by individual physicians or medical practices. The frequency with which physicians and medical practices switch among sources to obtain the lowest price varies. Payers have not traditionally offered physicians additional services such as case or disease management. However, as some PBMs begin to move into the specialty pharmacy world, they are applying some outpatient drug management tools to this arena.

Insurers have traditionally paid for drugs administered in the physician's office under a plan's medical benefit, paying physicians separately for the cost of the drug and its administration. There are four "prices" often mentioned in discussions of physician-administered drugs: (1) the actual acquisition cost, the amount the physician or other buyer actually pays for the drug; (2) the wholesale acquisition cost (WAC), a published number representing the amount wholesalers pay manufacturers for a drug, though they sometimes pay less; (3) the average wholesale price (AWP), a readily available published price for drugs, which is an integral part of pricing and payment formulas, although it is not derived from actual market prices; and (4) the Medicare allowable cost, the amount Medicare pays physicians for drugs they administer (AWP minus 5 percent). The actual acquisition cost of a given drug is often well below its published AWP and the Medicare allowable cost.

Private payers have followed Medicare, paying physicians from a low of AWP minus 20 percent to a high of AWP plus 10 percent. Although this payment theoretically only compensates physicians for the cost of drugs, in reality it also helps to pay physicians for practice costs associated with drug administration. Insurers, PBMs, and consultants view this "spread" (the difference between acquisition cost and third-party payment) largely as profit for the physician. Physicians, however, see the spread as barely covering their practices costs and crucial in offsetting under-payment for drug administration.

Information from interviews with key stakeholders also provided insight into new acquisition methods recently introduced by some private payers. It appears that these new approaches are being tried less often for oncology drugs than for other physician-administered drugs. These innovations include:

- Prescribed Distribution Channels. Some insurers have required that physicians acquire drugs through specialty pharmacy organizations working under contract to the insurers. These specialty pharmacies also "manage" the benefit as a PBM would for outpatient drugs.

- **Patient Purchase.** Less frequently, insurers require patients to purchase the drugs themselves under the health plan's regular outpatient drug benefit and bring them to the physician's office for administration. Payment to physicians for practice costs varies by insurer.
- **Revised Payment Levels.** Here, insurers have chosen not to become involved in the distribution channel, instead lowering the amounts they pay physicians for the drugs they administer. This change is usually accompanied by an increase in the fee paid to physicians for drug administration.
- **Utilization Management.** A few PBMs are scrutinizing physicians' prescriptions for drugs administered in their offices to identify inappropriate utilization. Savings are created by the rejection of certain inappropriate prescriptions as well as the general discouragement of inappropriate prescribing. Such tight management remains rare. Increased utilization management is sometimes done in combination with changes in distribution channels or payment levels.
- **Preferred Drug Programs/Formularies.** For the few physician-administered drugs with generics or close substitutes, some insurers and PBMs/specialty pharmacies are beginning to use formularies.

Attitudes about the benefits and drawbacks of new distribution systems vary across groups. Insurers, PBMs, specialty pharmacies, and payers are generally developing these innovations and stand to benefit from cost savings. In doing so, however, they must address significant physician resistance especially from oncologists and particularly in geographic areas where physicians have the market leverage to avoid working with particular payers. In addition, insurers and PBMs face barriers to using these new methods including the need to address last-minute prescription changes and the trend towards more patient-specific treatment regimens that limit payers' ability to set drug preferences.

Patients are affected in fairly modest ways by these changes. While several of the tools could offer some patients out-of-pocket savings and utilization management can enhance the quality of care, patient purchase and prescribed distribution channels raise the potential for increased quality problems. In addition, patient purchase may present an added inconvenience to sick patients.

While physicians were generally negative about these innovations, some did cite advantages in having to maintain smaller inventories and not having to pay upfront acquisition costs. Physicians are concerned that the new systems do not adequately cover their practice costs and increase administrative costs associated with having to work with multiple organizations to acquire their drugs. Clinically, physicians express apprehension about the quality of drugs acquired from unfamiliar sources and more generally their loss of control over the distribution process.

These innovations in the acquisition and payment of physician-administered drugs present opportunities for cost savings both by lowering payers' acquisition costs and avoiding unnecessary utilization. However, attempts to implement them have faced several barriers, and many innovations are still in an experimental stage. Results from these pilot projects are mostly not yet available, although two companies reported savings in the range of 10 percent to 25 percent relative to previous expenditures.

Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector

INTRODUCTION

The Medicare Payment Advisory Commission (MedPAC) contracted with NORC at the University of Chicago and Georgetown University's Health Policy Institute to obtain information from stakeholders on the various manners in which physician-administered drugs, with a specific focus on oncology drugs, are purchased and distributed for privately insured patients. Reports by both the General Accounting Office (GAO) and the Office of Inspector General (OIG) have shown that Medicare's current payment rates for Part B covered drugs are well above physicians' acquisition costs.^{1,2}

Despite the relatively small number of outpatient prescription drugs covered by Medicare Part B, Medicare spent approximately \$6.4 billion for outpatient drugs in 2001, a figure that has been increasing at a rate greater than 20 percent per year over the last three years.³ As reported in our recent memo to MedPAC, rapid technological advancement has led to the development of new drugs and biologicals that will be eligible for coverage under Medicare Part B based on non-self administration.⁴ As the Food and Drug Administration approves more drugs covered under this Medicare benefit, Centers for Medicaid and Medicare Services (CMS) and MedPAC have become increasingly concerned with Medicare costs and payment issues for these drugs.

Current payment policies for covered drugs have several undesired effects. Medicare and its beneficiaries are placed under the financial burden of unnecessarily high payments. In addition, physicians derive substantial portions of their revenue through payments for drugs administered in their offices to compensate for insufficient payment for administration costs. Such cross-subsidization creates an environment where physicians have incentives for prescribing medication and prolonging treatment. However, Medicare is not alone in its skewed payment policies. Private insurers and health plans also pay physicians for drugs at rates that are higher than actual acquisition costs. To amend this situation, private insurance companies have been exploring new channels of distribution and payment for these drugs. This examination of the distribution channels and payment system for physician-administered drugs in the private market can help to inform MedPAC's discussion of options for restructuring payment for Medicare Part B covered drugs. This memo is organized around the following topics:

1. **Overview and Context.** We begin with a brief overview of pharmaceuticals covered under Medicare Part B and discussion of the payment system currently used. This will provide context for our research findings on payment and distribution systems utilized in the private market.
2. **Project Methodology.** We describe in detail our project methods and implementation. We conducted semi-structured interviews with key stakeholders from the various groups involved in distribution of and payment for physician-administered drugs in the private market.
3. **Key Findings.** We discuss what we have learned about the management of physician-administered drugs in the private market, in both the traditional acquisition and payment

system and new systems being explored. Attention is given to the possible costs and benefits of these new distributions methods to payers, physicians, and patients.

OVERVIEW AND CONTEXT

Medicare does not cover the majority of outpatient prescription drugs. However, under Part B, Medicare covers a limited number of outpatient pharmaceuticals from the following categories:

- Injectable drugs that are administered by a trained clinician
- Certain immunosuppressive drug therapy for transplant patients
- Hemophilia clotting factors
- Erythropoietin needed to treat anemia in patients with end-stage renal disease
- Oral anti-cancer drugs that are also available in injectable form
- Oral anti-nausea drugs for patients receiving Medicare-covered anti-cancer drugs
- Some drugs used in conjunction with durable medical equipment, for example nebulizers used to administer inhalation therapy drugs (e.g., albuterol) for treating respiratory conditions.
- Injectable osteoporosis drugs are covered in specified circumstances for women under Medicare’s home health coverage.

The current payment system is based on the average wholesale price (AWP) of covered drugs. However, as discussed in greater detail later in this memo, AWP has never been regulated and is not necessarily the actual acquisition cost for physicians and providers. For “single-source” drugs (i.e. those without generic equivalents available), Medicare reimburses at 95 percent of a given drug’s AWP. For multi-source drugs where several AWP’s exist, payment rates are set at the lowest of the average of all generic forms of the drug or the lowest band-name product. In the past, individual Medicare carriers calculated AWP’s, leading to variation in payment rates. To make pricing consistent across carriers, this year CMS established a single drug price (SDP) for Part B covered drugs. As with other Part B benefits, patients are responsible for a 20 percent copayment, while Medicare pays the remaining 80 percent (where the 100 percent total is 95 percent of AWP).

The current project explored the ways in which the private market has managed the purchase, distribution, and payment of physician-administered drugs. Of particular interest to MedPAC are recent innovations in these processes for the private market.

PROJECT METHODOLOGY

We conducted 16 structured interviews with key stakeholders and others knowledgeable about the ways in which physician-administered drugs are purchased, distributed, and paid for in the private market. Interviews were conducted by telephone and lasted approximately 45 minutes. The project team developed a list of questions that served as a starting point for the interviews with

our respondents. The list of questions provided structure to the conversation, but allowed enough flexibility for respondents to focus on their areas of expertise.

To develop the interview protocol, we reviewed MedPAC staff papers, recent articles in trade newsletters, and relevant reports from the General Accounting Office and the HHS Office of the Inspector General. These sources provided initial background about both traditional distribution channels as well as the new approaches being used. The interview questions are included as Appendix I to this report.

In coordination with MedPAC, we identified individuals through a variety of means, getting names from trade associations and professional societies, references in trade newsletters, suggestions from MedPAC staff, and personal contacts. We contacted these individuals to see if they would be available to participate in these interviews. Moreover, through our initial contacts, we requested suggestions for additional contacts. We conducted 16 interviews with 27 stakeholders. Respondents were sampled from several relevant groups, including 4 oncologists, 2 health plans, 2 pharmacy benefits managers (PBMs), 3 specialty pharmacy companies, 1 wholesaler, 1 group purchasing organization, and 3 consultants.

At least two members of the project team conducted each interview. One senior member of the research team led the interview, and a junior member took notes on the interview and served as backup to the lead interviewer. Whenever possible, two or more senior team members participated in the interview, one as lead and the others as backup. The lead interviewer started each conversation with a brief review of the project. On most of the interviews additional senior team members listened in and participated in the questioning. The team reviewed the interview notes and conducted informal content analysis on the results to determine what was learned from each topic covered in the interview. The report summarizes these results.

Through the interviews, we sought to examine the following themes:

- The manner in which physicians acquire physician-administered drugs. Specific issues examined included identification of the existing sources of these drugs, the various organizations physicians may partner with to obtain them, the interplay between physicians and insurers in determining which sources to utilize and who is responsible for purchasing the drugs, and the relative effects of each distribution method for patients, physicians, payers, and other actors.
- How key players in the drug distribution system – insurers, PBMs, pharmacies, group purchasing organizations, and physicians – interact. Topics explored were physicians' purchase of other services (e.g. dispensing services, obtaining prior authorization from insurers, providing patient support, etc.), whether purchase of these services is insurer mandated, and liability concerns surrounding inventory maintenance.
- The method of payment for the purchase and administration of these drugs in the private market. The focus of this section was on traditional and new payment methods for payment, price savings that have resulted from new payment methods, and whether specialty pharmacies and PBMs use formularies.

Because prescriptions related to the treatment of cancer represent 80 percent of Medicare Part B drug payments to physicians¹ we focused on oncology drugs as a major class of physician-administered drugs in both the selection of stakeholders as well as the in the development of the interview protocol.

KEY FINDINGS

The following sections present the key findings from our interviews. We first discuss traditional acquisition methods for physician-administered drug, then we describe payment mechanisms for these drugs, and conclude with a discussion of newer innovations in acquisition and payment methods. Within each section, findings are grouped according to specific topic areas from our the interview protocol.

Traditional Acquisition Methods for Drugs Administered in the Physician Offices

The first questions we asked respondents were about traditional acquisition methods that physicians used to obtain drugs to be administered in their offices and the distribution channels by which those drugs make their way from the manufacturer to the physician's office. Here we asked about methods that have been in use for some period of time, not new methods recently introduced by insurers or other payers.

How have physicians traditionally purchased drugs that require administration in their offices for privately insured patients?

Our interviews underscored that physicians use a complex and varied approach to acquiring physician-administered drugs. Traditionally, there have been four main methods by which doctors procure these medications – through manufacturers, wholesalers, group purchasing organizations (GPOs), and local pharmacies. Typically, pharmacy benefit managers (PBMs) have not been involved. These methods continue to account for the bulk of oncology (if not all physician office-administered) drug purchases.

- 1) **Manufacturer:** Physicians can buy the drugs directly from the manufacturer and maintain an inventory appropriate to their practice in their own storeroom. In this situation physicians usually accept the price quoted by the manufacturer, although some physicians do shop for prices at times (for example, a large practice that is a high volume user of certain drugs). Manufacturers set prices within federal guidelines that require similar buyers be charged similar prices. One respondent said that physicians are most likely to get the ancillary drugs, as opposed to chemotherapy drugs, directly from the manufacturers.
- 2) **Wholesaler:** Physicians can buy their drugs through wholesalers. In addition to general wholesalers, there are apparently four or five that specialize in oncology drugs. Some physicians use small specialty wholesalers who market directly to oncologists' offices. Unlike large wholesalers, these firms tend to serve a single locality or region. A typical physician would order through a specialty wholesaler about twice a month and receive their drugs overnight via express delivery service. The specialty wholesaler orders the drug from the manufacturer or larger wholesaler. Although the physician may realize some price discount in acquiring their drugs through a specialty wholesaler, the main benefit to physicians is being able to use a single agent for drugs from multiple manufacturers with whom they deal. Unlike larger wholesalers, specialty wholesalers will deal with physician practices of all sizes, including small offices.

Other physicians work with large, national drug wholesalers (e.g. McKesson, Cardinal Health, Amerisource) to purchase their drugs. Because of their scale, these wholesalers can achieve greater discounts for physicians than can local, specialty wholesalers. But

generally only larger practices (i.e., those with at least 10 to 15 physicians) have adequate business staff to work with national wholesalers to procure the drugs they administer.

- 3) **Group Purchasing Organization:** Physicians can contract with group purchasing organizations (GPOs) to purchase the drugs they administer. GPOs take different forms, ranging from large entities like US Oncology, which typically provides overall management of the practice, including procurement of drugs, to simpler purchasing cooperatives. By bringing physicians together in large numbers, GPOs are able to negotiate volume discounts from manufacturers or wholesalers. GPOs typically track prices and may work directly with manufacturers, rather than wholesalers, to get the best prices and to cut out the wholesaler markup. Typically GPOs only determine the acquisition price; they do not come in contact with the drugs themselves, which are shipped to the physician directly from the manufacturer or wholesaler. US Oncology, for example, contracts with a single wholesaler (Cardinal) for all its purchases. But in this case, US Oncology negotiates the prices directly with the manufacturer. The wholesaler handles the physical movement of the drugs from the manufacturer to the oncology practice. Physicians usually pay an annual fee to join a GPO.
- 4) **Retail Pharmacy:** Some physicians develop a relationship with a local retail pharmacy that orders drugs on the physician's behalf and may maintain the inventory until needed by the doctor. These pharmacies are usually community-owned (rather than chain drug stores) and are located in close proximity to the physician's office (e.g., in the lobby of the medical building that houses the physician's office). Although the pharmacy may be able to realize some price discount for the physicians, the main benefit to the doctors is the convenience of working with an agent who has pre-established relationships with manufacturers and wholesalers as well as the facilities to maintain inventory that can be readily transferred to the physician when needed.

Any given physician or medical practice can use any or all of these methods for any particular drug. They can use different methods of procurement for different drugs, and they can change the methods they use over time. One informant stressed that medical practices vary significantly in their business savvy, although larger practices are more likely to have the expertise in-house to develop a procurement strategy, using combinations of the methods outlined above, that assures ready access to needed drugs at the best acquisition price. For example, a physician's office might have an agreement with a large national wholesaler for general purposes, but also purchase drugs from a local pharmacy (typically at higher prices) in emergency or quick turn-around situations.

Do physicians typically shop around for a best price?

Our physician respondents generally did not report shopping extensively for price. They seemed more interested in obtaining an intermediary (wholesaler or GPO) that they liked and trusted and then sticking with that organization. One respondent suggested that he could save a little money shopping for better deals for multi-source drugs, but that he had little leverage in most cases. Another said that when he did check with alternative suppliers, he found lower prices no more than 10 percent of the time. A third said that price shopping took more time than was typically available in a small practice.

But other respondents (especially some of the wholesalers and specialty pharmacy representatives) noted that there are deals that doctors can obtain. And some suggest that shopping around is common, with some practices changing sources as often as daily. In

particular, certain products (e.g., blood products) are bought and sold like commodities. In addition, a large practice may get a good price from a wholesaler if they have a sufficiently predictable volume of patients to take short-dated drugs. The different responses may simply indicate that the world of physician-administered drugs is highly variable and that our small number of respondents limits our ability to draw firm conclusions on the prevalence of different patterns.

What types of inventory do physicians generally keep on hand?

Most physician practices hold a fairly substantial inventory. Two respondents reported that their larger group practices might keep an inventory worth from \$300,000 to \$500,000 on hand (probably about a week's worth of medication). These larger practices have a regular volume of patients that necessitates having a good supply to accommodate changes in treatments on the day the patient comes to the office. They also indicated that certain drugs are not used often, but may be needed urgently on short notice. Smaller practices apparently also keep some inventory for commonly used drugs, but may order other uncommonly used or expensive drugs just in time for use by a specific patient.

But there are incentives – both in terms of storage space and overhead costs – to limit inventories. Carrying too much stock is an expense. Practices typically get deliveries three times a week or even daily. A common approach would be to review their treatment schedules for the week and to make sure that they had adequate stock to meet that schedule.

Most practices, at least the larger ones, use an automated medication administration system (e.g., Pixis) for maintaining their inventories. These systems combine storage with inventory control software where the request for a drug is entered into the system, resulting in the appropriate drawer being unlocked to obtain the drug. The amount is recorded for billing and inventory control purposes.

Who is at risk for unused or spoiled inventory?

The risk for drug spoilage depends on where the problem occurs and the particular distribution method used. Apparently, some manufacturers will accept the return of drugs that have been held past their expiration dates; others may give partial refunds if drugs are returned when the expiration date is approaching. According to one respondent, these returns require contract provisions at the time of purchase. But one specialty pharmacy company told us that if they ship drugs to a physician for the purpose of general inventory management, the physician's office is responsible for out of date inventory. If they ship the drugs to fill a prescription for a particular patient, the pharmacy company absorbs the risk. If drugs are spilled or otherwise spoiled in the physician's office, however, the physician is typically at risk for that unused inventory.

The general sense from our interviews, however, was that the chance of spoiled or out-of-date drugs is small. Almost all cancer drugs are shipped unmixed and have a shelf life of one to three years. While many oncologists maintain some inventory, it is usually not large enough to make drug expiration common. Larger practices have drug-dispensing machines that also perform inventory control and prompt them to reorder when needed. Overall, our respondents said that good inventory management is important.

What is the risk of waste from multiuse vials of drugs?

Manufacturers ship some drugs in multiuse vials. Many payers recognize this and will pay the physician for an entire vial, even though the patient may need only a portion of the drug contained in the vial. Larger practices may have both the inventory system and volume of patients necessary to use these products efficiently. In some cases, they may profit when two insurers each pay for the entire vial. In other situations, payers or GPOs may manage inventory from multiuse vials carefully to save everyone money.

How is quality maintained? Who mixes the drugs?

One reason that physicians often try to arrange for a single supplier to procure the majority of their drugs is for quality control purposes. Several respondents mentioned recent cases of counterfeit drugs or fraud in the supply chain. Physicians and some of the GPOs they work with felt strongly about the need to work with regular partners to reduce the risk of encountering serious quality problems. Although some anecdotes were reported of drugs being shipped to the physicians already mixed, the norm is clearly for the physician offices to mix the drugs as they are needed.

What other case or disease management services do PBMs and insurers make available to physicians who administer specialty drugs?

Our interviews suggest that “softer services” such as case management are more the exception than the rule for specialty pharmacy drugs. The organizations that are involved with distribution (wholesalers) do not get involved with these other services. Some larger PBMs that are beginning to move into the specialty pharmacy world by integrating physician-administered drugs into the outpatient drug benefits they manage are able to identify potential interactions among any medications that the patient receives. Some insurers and specialty pharmacy organizations establish pharmacy networks to help move drugs from physician administration to self-administration (and hence from medical benefit to pharmacy benefit). However, this is generally not occurring in cancer since a medical professional still must administer most therapies. Lastly, our interviews suggested there might be great potential to improve quality and save money by identifying inappropriate uses of physician-administered medications. Realizing these benefits requires both a mechanism, such as National Drug Code (NDC) codes, to identify the dose and strength of drugs prescribed and a physician-administered drug benefit that is tightly managed. A few respondents pointed out that many of these “soft services” have the potential to create substantial savings over time, but will take longer to be realized than savings from a reduction in payments.

Payment for Drugs Administered in Physician Offices

Prior to some of the recent innovations, insurers covered drugs administered in the physician’s office under a plan’s medical benefit, not its pharmaceutical benefit. This has meant that the physicians were paid for both the cost of the drug and for their services in administering the drug.

By contrast, most outpatient drugs are paid as part of a health plan’s drug benefit. Increasingly, plans have engaged PBMs and similar organizations to manage their outpatient drug benefits through the use of formularies, prior authorization, and related tools. In the last few years, insurers and their clients become more concerned about the growing number of new physician-administered drugs and believe that there are significant opportunities for cost savings. As a

result, some insurers have begun to work with PBMs, specialty pharmacies, and other organizations to alter how these drugs are provided to physicians and how they pay for them.

How do private insurers pay for physician-administered cancer drugs?

Four types of drug “prices” enter into discussions of how physician-administered drugs are acquired and paid for: actual or “dead” acquisition cost, average wholesale price, Medicare allowable price, and wholesale acquisition cost.

- **Actual or “dead” acquisition cost** is the amount the physician actually pays for the drug under the traditional system. It can also refer to the amount that is paid by the specialty pharmacy or other organization (usually under contract with the payer) to acquire the drug for the physician. It does not include any allowance for the physicians’ practice costs.
- **Average wholesale price (AWP)** is a reference amount that is described as not an average, not really wholesale, and not really a price. However, it is one of the few readily available published amounts for each drug and hence, has become an integral part of pricing and payment discussions. Two private firms, Red Book and First DataBank, publish AWP’s for each NDC code, i.e., for each form and strength of a given medication. The AWP itself can vary substantially between Red Book and First DataBank, so the payment to physicians depends on which source the payer uses. One respondent provided an example where the First Data Bank AWP was \$62 and Red Book AWP was \$325. Private insurers and Medicare’s carriers have typically handled this by taking the lowest of the AWP’s.
- **Wholesale acquisition cost (WAC)** is a published number representing the amount paid by wholesalers to manufacturers for a given drug. However, some manufacturers sell drugs at a price below WAC to some distributors.
- **Medicare allowable cost** is the amount that the Medicare program pays physicians for drugs they administer. For most drugs, it is AWP minus 5 percent, an amount that in theory compensates the physician for the cost of the drug. In practice, it is now recognized that this payment also helps to compensate the physician for the practice costs associated with its administration.

None of these four prices represents a standard amount that private insurers pay physicians for drugs they administer. However, given Medicare’s dominance as a payer, most private payers have followed Medicare’s lead and pay physicians based on the AWP.⁵ Under both the traditional system as well as the various innovations outlined below, payment amounts range greatly. A further complication arises from the fact that AWP is recorded using NDC codes, while claims are filed using the broader J-codes that are part of the HCPCS coding system normally used for physician claims. Whereas NDC codes are assigned to each dose and strength of a particular drug, J-codes are aggregated across several NDC codes representing different manufacturers or container sizes. Hence, the payment depends on how the payer “crosswalks” J-codes to NDC codes.

The percentage of AWP that insurers are willing to pay physicians also varies. Respondents cited payment formulas as high as AWP plus 10 percent and as little as AWP minus 20 percent. Our informants indicated that these payment formulas vary by drug and by purchaser.

Physicians further point out that Medicare and some private payers require patient coinsurance on the drug charges. Under Medicare, the patient is responsible for 20 percent of the charge. Thus, if they are unable to collect the coinsurance, their payment is reduced.

How are physicians compensated for expenses incurred in administering a drug?

Like Medicare, private insurers typically make a separate payment for administration of the drug. But as with Medicare, physicians feel these payments fall far short of the actual cost of administering the drug.

What is the “spread” between acquisition cost and third-party payment?

We heard two contrasting stories from our interviews. Representatives of insurers, PBMs, and consultants who are familiar with this market uniformly and strongly believe that physician-administered drugs represents a significant area of revenue and profit for doctors. In their view, this profit results from the “spread” between the payment price and the actual acquisition price paid by the physicians. Although acknowledging that some of this spread compensates the physician for practice expenses (inadequately paid for under fee schedules), they view the spread as a source of profit to physicians. Two respondents told us that drugs represent between 50 percent and 60 percent of income for oncologists

By contrast, the oncologists with whom we spoke and some of the group purchasing organizations with whom they contract stressed that the margins they receive (relative to acquisition costs) on physician-administered drugs are crucial to offset under-payment for drug preparation and administration, follow-up with patients, and the infrastructure they must maintain in their offices to provide these services. They further told us that the “spread” was barely adequate to cover these other costs, which have been growing as more steps are taken to ensure the safety and quality of the drugs. In fact, they report losing money on a significant portion of the drugs they administer. They also insist that neither the price nor the spread are factors in decisions about treatment.

It is difficult to sort through these two differing stories and declare that one or the other is “true.” We note that this is a common result in studies of physician payment. Generally, it is impossible to declare one perspective or the other as correct because the issue comes down to alternative philosophies about physician compensation and different views on the appropriate accounting for various services for which there is no specific source of payment. This discrepancy in how payment is characterized is a major reason that making changes tends to be so difficult.

Innovations in Acquisition and Payment Methods

The second set of questions addressed new acquisition methods that have been more recently introduced by insurers or other payers. We asked about how these new methods worked and what modifications they imposed on the traditional approaches in areas such as inventory control. Finally, we asked for reactions to these new methods – whether based on actual experience with them or impressions about what worked and what would not work.

What sorts of innovation in procuring these drugs have private payers introduced in recent years?

Some of the first developments in specialty pharmacy begin about seven or eight years ago with emergence of firms working with the manufacturers of newly approved biotechnology drugs.

Often these new enterprises were part of existing companies including large wholesalers such as McKesson. Because some of these drugs were developed by relatively young biotechnology firms with little experience in the launch and marketing of new drug products, the manufacturers sometimes contracted with specialty pharmacy organizations to establish a distribution chain, including networks of pharmacies trained in how to dispense the products and in working with patients and doctors on appropriate use of the products. They also worked with physicians, patients, and insurers to win coverage and establish payment levels for the drug. As the following examples indicate, with time these firms and other specialty pharmacy companies that entered the market have come to work for insurers.

The innovations in drug procurement and payment that some insurers are beginning to use today include attempts to realize volume discounts in the acquisition costs of drugs (that are passed, at least in part, onto the payer) and, to a lesser extent, attempts to reduce medication uses not supported by clinical evidence. These new approaches are also designed to squeeze down the “spread” or profit margin that they perceive as widespread with physician-administered drugs.

Two respondents, who represent a wholesaler and a specialty pharmacy firm experienced with the new approaches, said relatively few have been tried in oncology compared to other specialty areas that use physician-administered drugs. The differences are both clinical and political. The administration of oncology drugs involves a greater number of ongoing clinical decisions, with frequent changes in drugs and dosages based on how the patient is doing. In addition, oncologists can usually bring more pressure to bear on health plans and others because of the high profile that cancer treatment brings.

To design and implement these programs, insurers are working with a mixture of PBMs (or their subsidiaries that focus on specialty pharmacy) and specialty pharmacy organizations. The innovations in the drug distribution system include the following:

- 1) **Prescribed Distribution Channels:** Some insurers have contracted with specialty pharmacies to perform a variety of services including purchasing of drugs from manufacturers, providing them to physicians as a wholesaler or pharmacy, and “managing” the benefit as a PBM would do for an outpatient drug benefit. One variant of this model is to designate a single specialty pharmacy vendor that all physicians would be required to use. In other cases, physicians may be offered a choice of more than one designated vendor.

Among our interviews, the relationship between one specialty pharmacy and a health plan with significant market share in its region illustrates this new method. For several years, oncologists treating this insurer’s patients have been required to purchase their drugs through the specialty pharmacy, which delivers them to the physicians’ offices unmixed within one to two days. In some cases, physicians treat patients with drugs in their inventories and the specialty pharmacy replaces the medication. In cases where physicians do not have the drug in stock, the specialty pharmacy dispenses it labeled for that specific patient.¹ In some cases, the order and delivery may cover an entire course of

¹ Although there is no financial difference from the perspective of the doctor or specialty pharmacy between the pharmacy shipping the drug for a particular patient prior to its administration and shipping the drug after the patient receives treatment to replenish the doctor’s inventory, the latter requires that the

chemotherapy, but it may be more common to handle each session separately because of frequent changes in the specific drugs and dosages for a given patient.

In this example, the specialty pharmacy also collects basic diagnostic information with the order and for some conditions compares this information against pre-established treatment guidelines. When a prescription appears to be in conflict with these guidelines, the specialty pharmacy alerts the insurer to decide whether the treatment is appropriate under the patient's insurance contract. On a monthly basis, the specialty pharmacy provides reports to the insurer about the drugs it has dispensed. Unlike the majority of private insurers, who are limited to the use of J-codes to adjudicate medical benefit claims, this firm has the capability to handle claims based on NDC codes. The use of these codes allows the insurer to examine doses and strengths of the drugs dispensed, information not normally captured by the J-codes. In this case, the insurer is trying to save money through both price discounts and utilization management.

- 2) **Patient Purchase:** In a small number of cases, insurers require patients to purchase their drugs (usually in a freeze-dried, unmixed form) at a preferred pharmacy and bring to the doctor's office for administration. This method allows the insurer to pay for the drug under the plan's pharmacy benefit and pay whatever price the plan's PBM is able to achieve from the manufacturer and pharmacy. Insurers adopting this approach vary in how they pay oncologists for administration. In most areas where this has been tried, oncologists have complained that they cannot cover their practice costs nor vouch for the integrity of the product. One oncologist reported hearing that the delivery company sometimes left drugs on a patient's doorstep, making proper storage difficult or impossible.
- 3) **Revised Payment Levels:** Some insurers have chosen not to become involved in the distribution channel, but have lowered the amounts they are willing to pay oncologists for the drugs they use in their offices. For example, instead of paying for whatever a physician might bill, the insurer may only pay a standard amount, e.g., AWP-10%. Or if they previously set payment at, say, AWP-5%, they might lower it to AWP-15%. Several interviewees commented that payment levels range significantly, citing payment rates from a high of AWP+10% all the way down to AWP-20%. The fee received by the physicians for administering the drug is often increased at the same time. One specialty pharmacy company gave an example where the payment for the drug was lowered by \$200, while the fee for administering the drug was increased by \$100. These amounts vary by drug, by insurer, and by the relative power of oncologists in a given geographic area to decide if they are willing to work with a given insurer.
- 4) **Utilization Management:** Some PBMs are also closely scrutinizing physician orders for drugs they administer in their offices to identify inappropriate utilization. We interviewed a representative of one PBM, a subsidiary of a large managed care firm, which has a tradition of very tight management of outpatient drug benefits through a closed formulary. In our interview, he noted that they look at the specific drugs

specialty pharmacy have a wholesale license, while the former requires a pharmacy license. In addition to this legal difference, the latter also helps an oncologist who maintains an office-based inventory to keep that stock of drugs fresh.

prescribed and verify whether the medications correspond to the patient's reported conditions and diagnosis (sometimes requesting review of the medical record). Although this form of aggressive management of specialty pharmacy drugs seems to be the exception, our respondent indicated his belief that there is significant use of oncology medication that is not supported by medical evidence. He believes there is great potential for cost savings, more so than from price reductions.

From our interviews, such tight management of utilization of physician-administered drugs has been the exception. However, some other PBMs are also beginning to manage physician-administered drugs paid for under the health plans' medical benefit as they would an outpatient drug benefit. Most of their efforts have focused on drugs dispensed as part of the health plans' home health benefit. To date they have done little in oncology. Officials at one large PBM told us they are rolling out their specialty drug program slowly and have avoided the cancer area for the most part, focusing on human growth hormone, hemophilia, interferons, and other drugs. In part, they see cancer drugs as so specific to patient conditions that they are more difficult to manage using traditional PBM methods. It also takes time to develop good data on appropriate utilization rates. In addition, they have wanted to avoid the substantial physician "push back" that would ensue among oncologists. But they do include some drugs ancillary to cancer treatment, such as drugs in the erythropoietin family, in their new specialty pharmacy program. Under this program, the PBM arranges for the drugs to be purchased and dispensed to the physician's office with a volume discount. It also provides counseling to patients (particularly for cases where drugs that can be self-administered after appropriate training) and performs some drug utilization review to identify potential interactions with other medications the patient is taking.

One informant pointed out that utilization management can yield two types of savings: those that come from cases where specific, inappropriate prescriptions are rejected, and those that come from the discouragement of inappropriate prescribing before it happens.

- 5) **Preferred Drug Programs/Formularies:** Some insurers and their PBMs/specialty pharmacies are beginning to use formularies for those oncology drugs with generics or close substitutes. One insurer indicated that while many cancer therapies are new drugs with limited potential for inclusion in a preferred drug system, there are more multi-source products than conventional wisdom would indicate. As mentioned above, there is greater potential to use formularies for ancillary oncology products such as drugs in the erythropoietin family, other blood regulators, and anti-emetic drugs than there is among anti-cancer therapies themselves. While most of the experts interviewed indicated that the potential for using formularies and similar preferred drug systems would grow with time, one clinician expressed his belief that the number of multi-source drugs is shrinking. In the short term, this oncologist may be correct given the number of new anti-cancer therapies approved in recent years. In the longer term, however, the approvals of "me too" drugs and generics may increase price competition. But the low prevalence of many forms of cancer may limit the market for this type of development.

One respondent suggested that these new approaches will be implemented more easily for injectable drugs rather than infusible drugs. Infusible drugs typically involve more clinical decisions at the time of administration, so some of the new approaches will be harder to implement.

What are the reactions of different parties to these innovations in the methods of drug distribution and payment?

Our respondents expressed a wide variety of views on the innovative methods for distributing and paying for physician-administered drugs. For the most part, physicians strongly disliked the changes, while insurers and some of the specialty pharmacy companies were strongly counting on these programs to control costs. Others, especially wholesalers, are relatively indifferent. While some potential benefits and drawbacks are specific to a particular innovation, others may be common to several or all of the innovations.

Insurers, PBMs, Specialty Pharmacy Companies, and Payers

The insurers, PBMs, specialty pharmacy companies, and the employers who contract with them, are generally the ones that are pushing innovations in the distribution chain. For them, the major potential benefit is cost savings.

- Prescribed distribution channels, patient purchase, new payment levels, and preferred drug programs are designed in part to save money by achieving better volume price discounts from manufacturers or wholesalers or by reducing or eliminating the spread between how much physicians pay for drugs and how much payment they receive. Achieving price discounts is the same strategy that GPOs have traditionally used, except that here the insurer, not the physician, is deciding how much of a margin on top of the acquisition cost of the drug that the physician can receive. Normally, they can increase the administration fee for the physician by a lesser amount than the drug price is lowered to accomplish savings. The more active PBMs or specialty pharmacy companies among our respondents are enthusiastic about their ability to get cost savings.
- For the small subset of drugs with close therapeutic substitutes or generics, formularies and related preferred drug programs offer the opportunity for payers to obtain additional volume price discounts. With time, more drugs may have “me too” equivalents or generics, thus increasing the potential benefit to insurers looking to save money.
- Utilization management offers insurers the potential to save money by identifying clinically inappropriate uses of physician-administered drugs. This type of management is common for self-administered drugs, but has not been used much in the past for physician-administered drugs. Prescribed distribution channels, with their tight management of physician administered drug benefits, can also provide the opportunity to examine utilization, especially if they use NDC codes that capture dose size and strength of dispensed drugs (rather than the less specific J-codes usually used for payment).

In order to achieve the desired savings, insurers or PBMs face numerous barriers that make it more difficult to implement some of these new procurement and payment methods:

- The J-codes used by Medicare and most private health insurance to pay claims for physician-administered drugs can limit the effectiveness of prescribed distribution channels, new payment levels, and utilization management. Because they are aggregated across several NDC codes, J-codes mask important information needed to manage utilization. Their use limits the insurer’s ability to examine physicians’ prescribing patterns and to make sure they are providing or paying only for the amount of drug that a patient uses. Furthermore, many physician-administered drugs are newly approved products, and there can be significant delay in the assignment of a J-code after FDA

approval. In the interim, claims for such drugs use a “miscellaneous” J-code that further inhibits the ability of a PBM to manage the benefit. By contrast, claims processing of outpatient drug benefits rely on NDC codes that are specifically assigned to each dose and strength of an FDA-approved drug. Insurers that use prescribed distribution channel methods have some ability to dispense using NDC codes (and one respondent does so), but the insurers paying physicians for drugs they purchase must rely on J-codes.

- Insurers can face resistance from physicians – especially oncologists – to most of these innovations. The physicians’ concerns, which include their ability to cover their practice costs and assure the quality of drugs administered, are discussed in greater detail below. In one case, physicians closed down their office-based practices for three months and shifted treatment to the hospital outpatient department. This raised the cost of a chemotherapy session from \$3,000 to \$5,000. The ability of insurers to force physicians to accept these new methods depends on the relative clout of the physicians and insurers in the particular geographic region, i.e., how uniformly can the physicians act to resist these methods? Do the insurers have sufficient market share that the physicians must accept their patients? At least one respondent noted that resistance can be overcome, but it requires considerable effort and outreach. Several respondents noted that, among the different parties, oncologists have the greatest leverage in these disputes.
- In some cases, insurers adopting prescribed distribution channels have chosen to address some physicians’ financial concerns, thus lowering the potential cost savings. In these cases, they procure the drug at a cost less than what the physician would pay on his or her own, but pay physicians the same margin in absolute dollars to cover preparation, administration, and overhead. For example, a physician purchasing drug X on his own may pay \$90 and bill the insurer \$100 to cover his practice costs. The insurer, using a prescribed distribution channel, may pay only \$80 to acquire the drug, but still pay the physician \$10 to cover practice costs.
- When insurers take more control of drug distribution, problems may arise from a last-minute change of orders based on an assessment of the patient’s medical condition on the day the drugs are to be administered. In some cases, this may mean that drugs shipped for use by a particular patient are wasted, adding to the insurer’s costs. This is less of an issue when the insurer replaces stock the physician holds.
- As mentioned in the previous section, the expiration of patents and the expectations of close therapeutic substitutes for many drugs associated with cancer therapy suggest that formularies and other types of preferred drug programs may yield further cost savings for payers in the future. However, respondents also reported that that biomedical research is subdividing cancers into more and more subtypes. To the extent that treatment regimens become more patient-specific, there may be limited opportunities for payers to prefer one drug to another for a given patient’s treatment.

Patients

Patients are affected in fairly modest ways by these changes, although under some changes the financial savings could be substantial.

- Utilization management offers potential enhancements to the quality of care. In addition to identifying inappropriate uses of drugs, tightly managed specialty pharmacy programs sometimes offer case management or instructions that allow drugs to be self-

administered. Furthermore, to the extent that insurers are integrating physician-administered drug dispensing into their outpatient pharmacy benefit (i.e., by having patients purchase their drugs at a retail pharmacy or by otherwise using the same PBM for both types of drugs), it increases their ability to identify drug interactions between physician-administered and self-administered drugs.

- Patient purchase may offer some patients an out-of-pocket savings by moving the drug purchase from the medical benefit to the outpatient prescription drug benefit. In some cases, the out-of-pocket outpatient drug payment may be set lower than the usual 20 percent coinsurance required for medical benefits. Of course, patients will still be liable for cost sharing on the physician's fee for administration.
- Under prescribed distribution channels, new payment levels, and preferred drug programs/formularies, patients would realize savings even if drugs continue to be paid under the medical benefit. By cutting the allowed charge for drugs, patients would owe 20 percent of a lower amount.

For patients, there are also some barriers or downsides to any of the new methods:

- The patient purchase approach subjects patients to the inconvenience of having to pick up the drugs at the pharmacy, pay any co-payment up front, and carry the drugs to the doctor's office where they are prepared and administered. For patients who are sick, this may be a particular burden. If they do not feel well enough to get the drug in time for a scheduled appointment, they could experience delayed or missed treatments.
- The prescribed distribution channels approach leads to the possibility that a last-minute change in the medications ordered can delay treatment while the physician awaits delivery of the new medication. Such a delay is a best an inconvenience for the patient and can have negative consequences for the quality of care.
- As discussed below, physicians worry about the quality of drugs that are procured through prescribed distribution channels or patient purchase, i.e., channels other the ones the physicians traditionally know and trust. To the extent that their concerns are justified (verifying these reports was beyond the scope of this project), patients would bear any medical risk associated with receiving bad drugs.

Physicians

Overall, physicians themselves report almost exclusively negative effects from these new methods. Other respondents, however, have identified potential benefits that come from being able to order and receive drugs quickly.

- Prescribed distribution channels also help assure that drugs are less likely to be "out of date" when needed for patients. Under these new systems, doctors either receive the drugs "just in time" to administer them to patients, or they use existing stock and update their inventory with newer drug. In addition, in the case of patient purchase, the physicians are no longer responsible for acquiring or maintaining any inventory of drug. Hence, it is always as fresh as the stock at the patient's pharmacy.
- Prescribed distribution channels and patient purchase also provide a minor financial advantage to physicians since they do not have to pay the acquisition cost of the drugs

upfront and then seek payment. In fact, some physicians may be glad to get out of the business of buying drugs, carrying the inventory costs, and then getting paid by insurers. If prices are going to be reduced regardless, they might prefer to eliminate the cash flow problems.

Physicians have expressed significant concerns about both the financial and clinical implications of most of the innovations being adopted by private payers.

- Under prescribed distribution channels, patient purchase, and new payment levels, physicians are concerned that they receive payment adequate to cover their practice costs, i.e., the preparation and administration of the drug and the use of infrastructure associated with providing the treatment. Under the patient purchase model as well, insurers would have to make sure that the payment to physicians is adequate to cover these costs. Under prescribed distribution channels and new payment levels, payers have to decide how much of a margin over a drug's acquisition cost they should allow physicians to cover such expenses. There has been significant discussion about how Medicare should pay for these costs – for oncologists in particular. As mentioned earlier, payment levels among private payers under both old and new distribution methods ranged broadly.
- At the same time, the oncologists interviewed acknowledged problems with the current system. Some thought it might be preferable to have a system that paid for administration of the drugs at a level that more accurately reflects practice costs (acquisition and administration of the drug and associated patient care costs) instead of the current system where they take a loss on these services but make it up in profits on drugs.
- Under patient purchase and prescribed distribution channels, physicians expressed serious concern over the quality of drugs that they did not procure themselves through the channels they have worked with in the past and trust. Most physicians had heard about recent cases of counterfeit drugs and were worried about being forced to work with new distributors with whom they lacked experience. Of course, the wholesalers, specialty pharmacies, and PBMs interviewed indicated that they trusted their distribution channels not to ship counterfeit drugs. Some physicians also noted that when drugs come “pre-mixed” in liquid form, they could not vouch for the strength or conditions under which they were prepared. Again, the wholesalers, specialty pharmacies, and PBMs interviewed downplayed this particular risk, indicating that almost all cancer drugs are dispensed in freeze-dried form and mixed in the physician's office.
- Physicians also object to losing the ability to have one organization handle all their drug transactions. As noted above, most practices generally work with a single GPO or wholesaler for this very reason. Physicians indicate problems stemming from keeping track of multiple insurers. They might have to maintain multiple inventories, although this problem goes away if insurers allow the option of providing replacement drugs, not drugs specifically labeled for a patient's use. But even in the latter case, physicians suggest that it will increase administrative demands. One potential step that could reduce the administrative problem would be increased use of electronic systems, although this may represent additional costs to some practices. Physicians also note that these new systems may preclude efficient use of multiuse vials. To a great extent, the issue for them comes back to a loss of quality control when there are multiple payers each with a different system.

What are the sources and magnitude of savings that newer methods of distribution and payment able to achieve?

As mentioned earlier, respondents cited two sources of potential cost savings – savings by paying less for the drugs and, to a lesser extent, attempts to avoid unnecessary utilization of physician-administered drugs.

Our informants voiced consensus that the prescribed distribution channels, new payment levels, and patient purchase approaches do yield lower per-unit prices, as one would expect. The concerns of physicians over the financial implications of these new methods bear further witness to this conclusion. Only one respondent, from a PBM, was willing to provide data on the savings they realize. The PBM studied one medical group that had previously been paid a flat AWP for injectable drugs and their administration. Under their new program, the PBM gave the medical group the option of using a prescribed distribution channel or accepting a payment level equivalent to what it could achieve if it purchased the drug. The PBM estimated that under the new system, it achieved an average of 14.1 percent off of AWP. Another company reported that it has experienced savings in the range of 10 percent to 25 percent by making adjustments on the price side, especially in non-oncology practices.

To date, attempts to save money through utilization management of cancer drugs are relatively uncommon for the reasons outlined earlier in the section on barriers. Thus far, they have been tried only by PBMs with a tradition of tightly managed pharmacy benefits and by some payers using the prescribed distribution channel approach. The same PBM that provided the cost savings estimates cited in the previous paragraph estimates that instituting a prior authorization requirement for injectable drugs yielded a 16.3 to 1 return on the actual cost of doing the prior authorization when overall health care costs were measured. The underlying idea is that prior authorization allows the payer to identify inappropriate utilization that could lead to more costly clinical complications. But it could not estimate the overall savings impact on drug spending.

The verdict is still out on whether these innovative approaches to acquisition and payment for drugs will be an improvement. Many are still pilot projects, and results are often unavailable. Beyond the view that infusible drugs and oncology drugs more generally are likely to be more difficult areas for change, it is too early to draw definitive conclusions.

Endnotes:

¹ United States General Accounting Office. GAO-01-1118 Medicare Drug Payments. September 21, 2001.

² United States Department of Health and Human Services, Office of Inspector General. OEI-03-00-00310 Medicare Reimbursement of Prescription Drugs. January, 2001.

³ MedPAC analysis lays out problems with AWP-based payments for drugs. Washington Health Beat. March 2003.

⁴ Drugs in the Development Pipeline. NORC at the University of Chicago and Georgetown University. Report submitted to MedPAC, April 15, 2003.

⁵ Exploring alternatives to AWP-pricing for Medicare-covered drugs. MedPAC staff presentation, January 16, 2003

Appendix I. Interview Protocol

General Questions on Methods of Distribution

1. How are physicians currently purchasing physician-administered drugs? Do they purchase all drugs from one source or do they shop around?
2. Do they work with wholesalers? Group purchasing organizations? PBMs?
3. Do insurers determine the source from which physicians will purchase drugs?
4. Do physicians or insurers purchase the drugs?

Roles of Insurers/PBMs/Pharmacies and Doctors

5. Do physicians purchase any services along with the drugs including dispensing services, obtaining prior authorization from insurers, providing patient support, etc?
6. Do insurers mandate any such services?
7. What kind of inventory do physicians generally keep on hand? Who is at risk for unused or spoiled inventory? Under selective contracting arrangements, do physicians keep separate inventories for different plans?

Reimbursement

8. How do private payers pay for these drugs? Do they pay separately for physician practice costs? How?
9. Do they [as physicians, insurers, PBMs, pharmacies, or group purchasing organizations] have any experience with new payment methods for these drugs?
10. What kinds of price savings are achieved by the different distribution channels? Does it vary by type of drug?
11. Is there any use of formularies by specialty pharmacies and PBMs?