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Session 26PD
Prescription Drug Update

Track: Health

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Summary: Pharmacy costs continue to increase at 18 percent or more per year for many health plans. Use of Cipro and antianxiety drugs has increased since the terrorist attacks. Panelists provide their insights on current topics. At the conclusion of this session, participants know what is driving the increase in prescription drug costs, what strategies are being used to try to control them, and what may be in store for the future.

MS. MARGARET WOOD WEAR: I am the chief actuary of Advanced Pharmaceutical Card System (PCS). I'm not sure if you are all familiar with what we do. We're the largest pharmacy benefit manager in the country, and, hence, I was asked to moderate the Prescription Drug Update session.

I have three excellent speakers, and we have three very interesting topics. The first speaker will be Grady Catterall. He's an actuary and senior manager at the Lewin Group, which is a consulting firm that deals mainly with Medicaid managed care and Medicaid plans across the country. He's going to cover pharmacy costs increases—their causes, projections and strategies for those increases.

The next speaker will be Mark Franzen. He's the CEO of IntelRx. IntelRx is a new company that provides insurers with data and tools to make intelligent use of pharmacy information in the underwriting process. Prior to joining IntelRx, Mark was the president and CEO of InfoTrust from 1995 to 2000. Before that, he was a

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†Ms. Jill Van Den Bos, not a member of the sponsoring organizations, is with Milliman U.S.A. in Denver, CO.

Note: The chart(s) referred to in the text can be found at the end of the manuscript.

health care actuary with Trustmark. He began his career as an assistant professor of mathematics at UCLA. He's going to be talking about using prescription drug data in the underwriting process.

And the last speaker is Jill Van Den Bos. She's with the Denver office of Milliman U.S.A. in the health practice area. She's worked there for about 10 years, and she works mainly in pharmacy pricing, pharmacoeconomics, long-term care pricing, and other areas. Prior to that, she was with the University of Colorado on a research team in the Institute of Behavioral Sciences. Jill is going to talk about pharmacoeconomics and information that comes from research areas around that and how we can better use that as intelligence in the world of pricing pharmacy benefits.

MR. GRADY CATTERALL: I'm going to be talking about the recent history of pharmacy benefit pricing and cost increases. I'll talk about the underlying causes for those rather steep increases. I'll go through the basis of cost projection methods for pharmacy benefits, and then I'll talk a little bit about some of the newer containment strategies that have come up.

INCREASES: THE NUMBERS

Why are we here? Over the last few years, the current member-per-year cost for pharmacy benefits, as recorded by Express Scripts, has risen from about $250 to around $500, and the trend has been in the midteens. They expect it to drop a little bit.

The dots on the last three bars (Chart 1) indicate the projected range of cost increases that Merck-Medco has come up with. So Express Scripts is on the optimistic side as far as Merck-Medco is concerned.

Looking at the global picture (Chart 2), the total year prescription drug expenditures have risen from $50 billion in 1993 to about $140 billion currently, and the rates have changed. The rate of increase in overall spending has gone as high as 20 percent. It's recently declined somewhat, and it is expected to decline a little bit more in the next couple of years.

Now, one reason given by a writer of an article on health affairs for why pharmacy benefits are rising so rapidly was that it wasn't previously a major part of the cost of benefit programs. But as this indicates, prescription drugs represent an increasing proportion of total health care costs. And this is from the CMS projections (Chart 3). Total personal health care expenditures, excluding investment and research, in 1993 were less than $800 billion; now they're about $1.1 trillion. They are expected to increase in the next few years to over $1.5 trillion.

Prescription drugs used to be around 8 percent, now they are up to 14 percent, of health care expenditures. So they make up a bigger piece of the health care pie, which makes it more important that we pay attention to that.

COMPONENTS OF COST INCREASES
Express Scripts has come up with the components of the cost increases for prescription drugs based on their data.

Inflation. Inflation has varied a little bit over the last few years, but it's hovered around 5 percent. Right now, it's a little over 5 percent. They're projecting 5 percent for the next few years.

Utilization, Drug Mix. The utilization adds another 5 percent or so. We have separate accountings for utilization and mix of drugs—and that's both therapeutic mix and strength mix— and the effect of new drugs for the last four years ending in 2000. For their projection going from 2001 to 2005, they combined those three elements: the new drugs, mix and the utilization. They expect a decreasing pharmacy trend. Right now it's still in the low to midteens. They're expecting it to drop to somewhere between 11 and 12 percent.

CAUSES

Aging. Let's talk about some of the underlying causes for these cost increases. The first is the aging population in the U.S.

Here's the current age distribution of the U.S. population, excluding people under 25, according to the Census Bureau (Chart 4). What they expect 10 years from now is shown here (Chart 5). Now, I've highlighted the 35–44 age group and the 55–64 age group, because you see a shift of about nine million people from the lower age group to the higher one. I've also semi-highlighted the 65–74 age group, because they gained an extra three million or so people: 1 percent of the population over the next 10 years.

The reason that's significant is this chart showing the per-member, per-year pharmacy cost by age (Chart 6). The lower curve is for 1997; the upper curve is for 2000. The age 40 amount that would apply to the 35–44 group was a little more than $400 per year in 2000. About nine million people are going to shift from a little less than $400 a year to almost $1,000 dollars a year, and we'll have a substantial increase among those whose current cost is about $1,400 per year—those are around within five years of 70 years of age.

More Third-Party Coverage. A second cause of pharmacy cost increases is expansion of third-party coverage. I was surprised to learn this. As recently as two decades ago, 70 percent of prescription drug spending was out of pocket, and only 30 percent was third parties.

Those portions have more or less reversed themselves. A little more than 30 percent remains out-of-pocket spending, almost 70 percent third party. And when you have a situation like that, it's easier for marketing by drug makers to have a

significant effect. The total amount spent on commercial activities rose from $9.2 billion in 1996 to $15.7 billion in 2000. That's a 70 percent increase, or about 14 percent per year.

Direct-to-Physician Marketing. About half the cost is the free samples they give to your doctor, and that's been valued at retail cost. So that overstates the cost to the pharmacy companies, but still that's the biggest part of their spending on promotion. Another 26 percent of their spending is on other commercial activities directed at physicians.

Direct-to-Consumer Advertising (DTC). Direct consumer advertising is still a fairly small portion. It's about $1 out of every $6 spent on promotion purposes, but it's a rapidly growing portion of the pie, and I think it has a very big impact on spending patterns. Then there's another 5 percent for hospital-based promotions and another 3 percent on medical journal ads.

Freebies to Doctors. First of all, we have direct-to-physician marketing or detailing. As I mentioned, two-thirds of that is free samples given to physicians with the intention of getting patients started on that drug. If the physician determines that a certain drug will be beneficial to a patient, he or she can just reach into their closet and grab some free samples of the drug, and that gives a leg up to a particular brand. Or it might even give a leg up to a brand drug over an equivalent generic drug.

There are also the perks that doctors receive—free travel, speaking fees at conferences and other gifts. There's some question in my mind about whether that has any effect. Most of the doctors I know just take the money and run and don't really pay much attention to who's providing it.

However, some doctors—and particularly some medical students—are trying to get away from all the freebies. There's an article in today's *Wall Street Journal* about that. A med student at Brown is swearing off of all the freebies from pharmaceutical companies and urging others to do so.

Free Info. Then there's the free information that the detailers, the salespeople, provide to doctors. And this is a valuable service, because doctors don't have time to keep up with all the new information that's coming out about new drugs. But while physicians do learn about available drug therapies, they don't really get the cost benefit analysis, because these detailers are there to promote their employer's drugs. So that's just the nature of the business.

More on DTC. Now, looking at direct-to-consumer advertising, the total amount has risen dramatically over the past few years. In 1994 it was about $250 million. It's risen to almost $2.5 billion in 2000. And if you look at print and other advertising, this has leveled off over the past few years. There's been an explosion in TV advertising.

Before I took a job at Lewin Group, I was working out of my house and spent a lot of time watching daytime TV. And if you do that, you'll see on many programs, when they turn to a commercial break, four or five ads in a row for prescription drugs. So there's really a big push being made by the pharmaceutical companies to get their products on TV in front of consumers. And there's some evidence that all this works.

If you look at the 25 most advertised drugs—and that's just talking about DTC advertising—the increase in sales from 1998 to 1999 was 42 percent. If you look at other advertised drugs, the increase was 16.3 percent. So spending more on DTC advertising works better than spending less.

As for the nonadvertised drugs, the spending for those drugs was only 10 percent. Now, there's a bit of a chicken-and-egg problem here, because it could be that the 25 most advertised drugs are most advertised because the pharmacy companies have determined they have the biggest profit potentials or sales potential. I think they act on each other. That's why they're chosen for promotion. But I think the advertising also helps to build the sales.

Direct-to-Patient Marketing. Then there's an aggressively new form of marketing, which the *Wall Street Journal* labeled "direct-to-patient marketing."

One example is health newsletters that are put in the bag when you pick up a prescription at the drug store. It will contain an advertisement that might be disguised as an article that will promote the current drug that the patient is using or a new form of that current drug or a rival drug for the same condition.

This health newsletter is generated at the point of sale. It's all computerized; so the articles and the ads might vary according to age and gender of the patient and even by insurance status. So they might push a different set of products to those who are covered by employer plans from those who are covered by Medicare and might not have prescription drug coverage.

Patenting New Old Drugs. A couple of examples were cited in the June 14 *Wall Street Journal* article on the topic. There's one newsletter that urged patients to consider switching from Ditropan to Ditropan XL because Ditropan is coming off patent and Ditropan XL has a new patent on it. It's just an extended-release version; otherwise, it's identical to the previous version. But it has a patent life of several more years, so the manufacturer is trying to encourage patients to switch to the form of drug that will still be patent-protected for several years.

Another health newsletter promoted Advair as an asthma treatment to patients who currently are using Singulair. So, in order words, if a patient goes to the drug store to pick up Singulair, there will be an ad in the bag for Advair saying, "Oh, why don't you try ours instead?"

Now, another kind of direct-to-patient marketing is pharmacies being paid to mail letters that say "From your pharmacist" to patients suggesting that they try a specific drug. As far as I know, it doesn't actually list the pharmacist's name, and the individual pharmacist might not be aware that this is going on in many cases. But a lot of large drug store chains participate in such programs. It's usually not the current drug, but it might be a new form of the patient's current drug or a rival drug for the same condition.

A couple of examples: This was reported in the *Wall Street Journal* on May 1. The article started out with a story about a woman who takes a daily Fosamax pill for osteoporosis and she got a letter that said, "From your—I can't remember the name of the store—pharmacist." And it listed the store's name, talking about how she might want to consider the new weekly dosage of Fosamax, because that way she doesn't have to worry about taking it every day. But the reason that it is being promoted is that the weekly dosage has an extended patent.

There was another letter that went out to patients currently taking Prilosec for heartburn. And this letter was promoting Nexium, the new heartburn drug from the same company, suggesting that patients switch to Nexium and even offering free samples. It did not contain the free samples, but it contained information about how you can get free samples of Nexium.

Now, this is one of the key causes of our failure to contain pharmacy cost increases, in my opinion: the ability of brand drug makers to thwart generic competition. They're doing this because they need to earn as high a return as possible on their shareholders' investments. The pharmacy companies have historically earned much more than companies in other industries; their stocks are very high priced, and they're under pressure to keep that up. Only about one-third of the drugs approved by the Food And Drug Administration (FDA) from 1989 to 2000 were new molecular entities. The remainder were for incremental modifications of existing drugs—old ingredients that were changed somehow—new salts or esters, which actually sometimes can have a very important effect in terms of reducing side effects or increasing effectiveness.

New combinations of active ingredients might continue—combine a drug for heartburn with an antibiotic or something like that. And when you do that and test it and prove that it's safe and usually effective on a condition, then you can get a patent extension.

The new formulations can be like the extended release version that I was talking about earlier for Fosamax or a new mode of administration. For example, BuSpar first came out as a pill, then they came out with a transdermal patch, and the patch had a single patent protection. So the makers of BuSpar spent a fair amount of money trying to convince people to switch to the patch.

Extending Patents. Then there's the general effort to defend and extend patents. I break this down into three steps.

Patent Everything

Step one is patent everything in sight. Drug makers try to patent manufacturing procedures, even the inner ingredients in their products. For example, a commonly used pill coating used for heartburn medication: a manufacturer tried to get a patent for that, even though it was already made by other companies and widely used and widely known about.

This also includes new indications for a given drug: if you show that it works on some condition other than the one for which it was originally approved, or if you show that it works on a new population. For example, if you show that it is safe and effective for children, then you can get an extension on your patent.

Many companies have even tried to patent the metabolites that are produced in a patient's body, which I think is just extraordinary. They're basically accusing patients of infringing on their patents if they swallow a medication and their bodies convert the medication into a metabolite that they have a patent on. That's never been tried in court. I don't think it would stand up in court, but it's an interesting tactic.

Orange Book Rush

Step two is to get everything into the "Orange Book." Drug makers submit info on their patents to the FDA. The FDA puts it in this big book listing all approved pharmaceuticals and all the patents that are tied to them. That's called the "Orange Book."

The FDA refuses, in general, to review these submitted patents, because they say that don't have the expertise. They're not the Patent Office. So they generally just take whatever is submitted by the pharmaceutical companies. As a result of this, many critics charge that the Orange Book contains many invalid or inaccurately reported patents.

30-Month Stay

So that's important, because the next step, which is triggering the 30-month stay, will keep generic manufacturers out of your market for two and a half years.

When a generic drug maker submits an FDA application, it has to notify the owner of each patent that's listed in the Orange Book for that drug that they are submitting this application, and they have to say why their drug doesn't infringe on anyone's patents.

For the principal patent, they usually will say, "Well, that patent has expired." There are a lot of subsidiary patents that I just described, and generic manufacturers will say, "That's not valid," or "That applies to something else," and so our drug should be approved.

But the patent owner can file a patent infringement lawsuit, and that triggers an automatic 30-month delay in FDA approval for the generic drug, unless a court rules otherwise. But the court cases tend to drag on much more longer than two and a half years; so regardless of the merits of the brand drug maker's case, they can win an extra two and a half years of protection that way.

If that fails, they also can file citizen petitions raising safety questions about the generic drug. The FDA turns down about 80 percent of those petitions, but they can still cause delays in approving the generic drug.

Again, the brand drug manufacturers are trying to protect their intellectual property. All they can be accused of is being very, very aggressive about it. And, in my personal opinion, they've stepped over the line. I mean, they are doing what they're supposed to do. They're trying to promote their products. They're trying to make a good return for the shareholders. I think the rules need to be changed a little bit.

Generics Getting Flattened. The result of all of these efforts by the brand drug manufacturers is that generic drug penetration has flattened out over the past few years.

If you look at 1997 versus 2000, the first three bars are for those under 65, the next three bars are for those over 65 in 1997 (Chart 7). Then you look at the corresponding numbers, and there's a percentage of drug spending that's spent on generics. These corresponding numbers for 2000 are almost uniformly lower than the numbers for 1997.

So the lives of the generic drugs in terms of market share have stalled. That's a big part of the cause of the failure to contain the cost. If you can't move enough people to generics, then you're going to have big bills for expensive brand-name drugs.

Developing New Drugs. A couple of other causes worth mentioning. First, the cost of developing a new drug is on the rise. It used to be that pharmaceutical companies said it cost about $500 million to do all the research and testing for a new drug. Somebody did a study last fall that said actually the figure has now risen to $800 million. However, some critics of the industry say if you account for it properly, including accounting for work done in government laboratories, it's actually much less. So there's some debate about that.

But it is very expensive to develop new drugs. And pharmaceutical companies have had trouble recently coming up with new drugs; so that's one reason they're trying to extend the patents on the existing drugs as much as possible.

Foreign Price Controls. Another factor that I think comes into play is that all other countries control drug prices. At the very least, most industrialized countries say that a drug maker can charge more for a drug in their country than they charge in other countries. There are usually some adjustments for national income and such.

Right now, some of these countries that impose price controls are going further and imposing price cuts. And when that happens, there's a good chance you'll see manufacturers raising U.S. prices, because this is the only place where they can raise prices.

PROJECTING PHARMACY COSTS

I'm now going to go over just some of the mechanics of projection methods for pharmacy costs.

We break down the plan costs into number of members times the cost per member, which is divided into scripts per member times the adjusted cost per script. And *that* cost is adjusted by the discount, which reduces the cost. Add on the fees by the pharmacy benefit manager (PBM) if there's a pharmacy benefit manager involved; and then you subtract the patient copayment. You also have to adjust for formulary rebates and PBM guarantees—there might be guarantees in the contract between the plan's sponsor or HMO and the PBM.

The data that you need to do this projection, the basic data, are scripts per member and cost per script—the historical levels and trends in those amounts. Separate data are needed for each category of spending, for example, retail brand drugs versus mail-order generic drugs and so forth.

The best source of data is plan-specific or group-specific costs. You have to adjust for utilization, unit cost trends, and demographic plan design changes that have occurred over the expense period. In the absence of such plan-specific data, you can fall back on national data supplied by all the big PBMs.

If you look at the bottom of these charts, a lot of the information came from the Advance PCS, other information came from Express Scripts, and yet other information came from Merck-Medco. They all produce reports on pharmacy benefit trends.

Looking at the scripts per member, what we are talking about is the number of prescriptions per member per month—often referred to as utilization. It may also include the days supply per script. That is, the days per member—which might be the measure of utilization—is scripts per member times days per script.

Average Wholesale Price. Then there's the ingredient cost per script. Generally, the tradition has been to use average wholesale price (AWP) for discounts and fees. These refer to gross costs. Nowadays, the AWP is often referred to as the sticker price, and it is, in fact, becoming less relevant.

Then if you were talking about benefits provided through a PBM, there are PBM discounts, which will be specified in the contract. They're usually expressed as a percentage off of AWP. It varies by category of drug, brand versus generic, level of dispensing, and retail versus mail-order.

As I was saying, AWP is becoming less meaningful as fewer payers are paying the sticker price. There's been a lot of debate about how this impacts Medicaid reimbursements for pharmacy benefits. And Medicaid directors are saying, "If it is based on the sticker price, that can just be an inflated number that nobody should be paying." So it's becoming a little more difficult to characterize drug costs.

Max Pricing. Maximum allowable cost (MAC) pricing was introduced several years ago for drugs available in generic form.

It's possible we might see a similar concept applied to brand drugs as fewer and fewer payers are paying the sticker price. MAC pricing limits payment or reimbursement to the cost of the generic form of the drug. So, in effect, it's similar to a mandatory generic substitution rule.

Then there's the expensing or administrative fees assessed on a per-script basis—again, varying by category of drug and mode of dispensing.

Fees. Then there are the other PBM fees such as for formulary management and utilization management programs. This often is expressed on a per-member, per-month (PMPM) basis or per case. Sometimes it's dealt with outside the overall PMPM projection.

Copayments. Then there are the member copayments. It might be a flat dollar amount, low for generic. You might have a three-tier or even a multiple-tier copay structure. So there's the lowest copay for generics, more for formulary or preferred drugs (brand drugs), and the most for nonpreferred brand drugs. Generally, the copay is less for mail-order, relative to the number of days supplied.

The member copayment might be a percentage of the prescription cost. It might have a specified minimum or maximum dollar amount. It may vary by category of drug. Previously, it was not useful for mail-order; however, with more plans and PBMs using reorder procedures online and having credit card information on file so that they can go to the patient automatically, it makes having a percentage copay for mail-order a little more practical.

Formula Rebates. Then there are the formulary rebates that PBMs get from the drug manufacturers based on how much the share of a given therapeutic class market that manufacturer's drug captures. The rebates may be retained by the PBM as a form of their compensation, or they may be passed on in whole or part to the plan sponsor. That's especially true with larger plan sponsors. It can be part of the PMPM cost calculation, or it can be estimated in the aggregate.

Guarantees, etc. Then there are PBM guarantees, contract performance, cost or risk cost risk sharing, and those are generally outside of the PMPM calculation.

Utilization Trends

Looking at utilization trends over the last few years, scripts per member have increased anywhere from 7 to 9 percent per year for retail and mail-order combined. Those are the most recent trends, and that's the projection for the immediate future.

If you're pricing retail and mail-order separately, doing the projection separately, you might want to have a slight downward adjustment for retail and an upper adjustment for mail-order—that is, if your mail-order program is successfully luring patients, weaning patients from the retail mode of dispensing.

COST TRENDS

Same Drug Inflation. The unit cost trend—in terms of the pure inflation for the same drug, same strength, same amount—has been running about 5 percent per year. The effective changes in mix of drugs dispensed, both the strength mix and the therapeutic mix—as switching from one drug to another, which might be more expensive—that's 1 to 3 percent per year. These figures are all from the Express Scripts 2000 drug trend report and Merck-Medco 2001 drug trend report.

New Drug Costs. The cost attributable to new drugs, according to Express Scripts, has more or less decreased from 1996 to 1997 (2.4 percent). It was 0.3 percent from 1999 to 2000—a rather dramatic drop in the most recent year for which they have data.

As I mentioned earlier, the drug manufacturers are having trouble coming up with new blockbusters. The average has been about 1.5 percent. So new drugs actually add 1.5 percent to your total drug cost.

So if you put all this together, the total projected annual PMPM cost increase over the next few years is in the 14 to 19 percent range. For some plans, it will be quite a bit higher. If, on the other hand, a plan imposes very stringent cost controls, it could be lower. One hopes they'll be lower.

CONTAINMENT STRATEGIES

Now I want to talk about a few containment strategies.

Tiered Formularies. I mentioned that the three-tier formulary is being replaced by multiple-tier formularies. Express Scripts started marketing a five-tier formulary last summer, starting out with the lowest copay for the less expensive generic drugs, a slightly higher copay for more expensive generics—and there's a lot of variation. Some generics are made by a lot of companies, some are made by just one or two.

Then you have a slightly higher copay for preferred brand drugs—that is, those nonformulary drugs that have negotiated discounts, but have a high value relative to cost. That means the PBM or somebody has to do some analysis of the benefit of that drug, and there are various ways the health economists measure that relative to the cost.

The next tier, with a higher copayment, is preferred drugs with a low value relative to cost or nonpreferred drugs with a high value relative to cost. Then the highest copay, which could be up to $50 per script, would be for nonpreferred drugs, nonformulary drugs that have been determined to have a low value in terms of clinical improvement relative to the cost.

Reference Pricing. Another tactic is reference pricing. This is where you fix the monthly benefit for each therapeutic class on the cost of some effective but low-price drug in that class, and you make the member pay any amount over that. This is widely used in Europe. It's being considered by some Blue Cross plans. I don't know if it's actually been implemented.

Formulary Exclusions. Then there are formulary exclusions. I talked about drugs that are just incremental modifications of old drugs. They need to go to the FDA for approval. Not only are they just slight modifications, but many of them show no statistically significant clinical improvement over existing drugs. But, still, if you have a new drug where there's some incremental modification or new entity and is safe and effective against the condition, even if it's not more effective than the existing drug, you can get it approved by the FDA.

So some formularies are excluding these second-generation or incrementally modified drugs that the drug makers allow with the intention of moving patients from the existing products that are coming off patent. Some plans are saying, "We're not going to let you do that. Your new drug doesn't really offer any extra benefits; so we're leaving it off our formulary." So if a patient wants to switch, they'll have to pay extra.

Step Therapy. Then there's step therapy, which has been around for a number of years. There's the step-up therapy, the step-up version, in which you start with the least expensive drug in a given class. Again, if that works, you stop there, and if it doesn't work, you try successively more expensive drugs in that category until the patient's condition improves.

There's the step-down version, in which you start with whatever the doctor thinks is most likely to be effective. And then once the patient's condition is stabilized, then you can try the less expensive drugs. And that's good for maintenance drugs—drugs that people have been taking for a long period, perhaps for the rest of their lives.

Stick vs. Carrot. Consider the stick versus the carrot approach. You either impose a higher copay for noncompliance, or, since you want to keep your members happy, and employers want to keep their employees happy, you might want to have a carrot approach in which you give a copay discount for compliance with a step-up program or a successful transition to a less expensive drug for a step-down program. You can work this out so that you still have an incentive to comply with these programs but it is perceived in a better way by the patient.

Physician Management. Last is physician management. Now, this is important because it is the physician who writes the script, who is mostly in control of which script gets filled.

Now, patients are often showing up at their doctor's offices asking about a particular drug they've heard about. And studies have shown that when a patient does that, he or she is more likely to leave the doctor's office with a prescription; but it won't necessarily be for the drug that the patient asked for, because physicians are aware of the need to control costs. So they'll often say, "Why don't you try this less expensive one first?"

There are various ways to get the physician's attention. There's a pharmacy management bonus, in which you pay a bonus to the physician if a drug utilization target is met. And it might be a drug utilization target for that physician or for the physician's group.

A profiling prompt is where the PBM identifies patients who could be switched to a less expensive drug. You look in your database and see which patients are on medications for which there are cheaper alternatives. You send letters—sometimes those counter detailers or academic detailers—to physicians. These are sort of antisalesmen. They're telling the physician, "Yes, we know the drug maker is sending people out to promote their drug. We want to tell you about the less expensive alternatives, just so you are aware of that."

One way that the counter detailers can be particularly effective is to distribute generic drug samples to physicians. So when the physician reaches onto his or her

shelf and picks out a sample for the patient, there's a generic drug available. And for that, the PBM has to work with the generic drug manufacturers. It's difficult to get free samples, because the generic drug manufacturers work on very thin margins. But if you can get that to work, then that can have an impact on costs.

MR. MARK J. FRANZEN: I'm going to switch gears a little bit. I want to tell you about two new underwriting approaches that are based on prescription drugs.

The objective of this presentation is to describe two new pharmacy-based underwriting approaches—underwriting tools—show how these tools are used, and show some of the benefits of these tools—benefits in improved risk selection, reduced loss ratios, and sales and profit growth.

The two underwriting tools that I want to describe are online individual pharmacy histories and pharmacy-based predictive models.

ONLINE PRESCRIPTION HISTORIES

Let me start by describing online prescription histories, and that starts with a data aggregator. A data aggregator is a company that's contracted with pharmacy benefit managers (PBMs) to obtain data and history on individuals. The data aggregator contracts with multiple PBMs to have access to this kind of data.

What really has allowed this concept to develop is the rapid consolidation of the PBM industry in recent years. Now, by contracting with a handful of PBMs, the data aggregator can have access to prescription records on the majority of Americans.

The data aggregator contracts with the pharmacy benefit manager and then establishes an electronic link with the PBM so that the data aggregator can query against the PBM's database in a nearly real-time environment. So we're talking about querying these databases in minutes and then putting those data in a common format.

Data Aggregation at Work. How does this process work? An applicant comes in to an insurer and first must authorize the insurer to access and review this kind of data. What this means is that as part of the application, the individual signs a release, and the release gives the insurer authority to access and review prescription information on behalf of that individual. This is a critical step because of privacy regulations, notably the Health Insurance Portability and Accountability Act (HIPAA), that have sprung up recently. This is the foundation of this process. You must start here. You must have the individual's permission before accessing their pharmacy history.

After the individual signs an authorization, then the identifying information on the individual is sent to the data aggregator. Typically, the identifying information is the person's name, Social Security number, and date of birth. That information is sent to the data aggregator, which then can electronically query the PBMs and bring

back information on the pharmacy history on the individual. Then that raw data, the raw claims data that are brought back from the PBMs, are presented to the underwriter via presentation and diagnostic software.

Here's what makes this process powerful: Prescription drug information is very indicative of the health status of an individual, and it's very predictive of the health status of an individual. The pharmacy utilization, the scripts per member, continues to go up at 7 to 9 percent. Scripts are more and more a part of treatment, and our common experience tells us that when we go to the doctor, you can't be treated these days without some kind of prescription.

So as utilization continues to rise, as pharmaceutical therapies become more widespread, the drugs that a person is taking becomes more indicative of their health status. As one doctor put it, "Tell me what somebody is on, and I'll tell you what they've got."

The first step is that Jane Doe, the applicant, comes in to the insurer and signs a release, giving the insurer the authority to review Jane's prescription history. Jane Doe's name and her Social Security number and date of birth are sent on to the data aggregator. The data aggregator queries the PBMs that are under contract and returns Jane's prescription history.

One thing to point out here is that it's important that the data aggregator have contracts with several PBMs that cover a wide share of the market. Jane may have changed employers several times over the past few years. The employers may have changed health plans over the past few years. The health plans may have changed PBM vendors over the past few years. Jane's prescription record might be scattered across several PBMs. So it's important that the data aggregator have contracts with many PBMs and the largest PBMs in the market.

Then those PBM data are returned to the underwriter via diagnostic and presentation software. This software makes an inference about the medical condition of the individual from the raw prescription data. For example, our Jane is taking Amerge and Allegra with the implied diagnosis of migraine and allergies. The software makes the determination or the inference of the diagnosis.

Status of the Idea. What's the status of this concept today? Well, there are two companies that are data aggregators. One is a company called Nex2, based in Salt Lake City; the other is a company called Lab One in Kansas City. Both of these aggregators have contracts with several PBMs, the major PBMs, and they have built the electronic linkage between the aggregator and the PBM. My company, IntelRx, develops diagnostic software and also integrates the PBM data into an underwriter's workflow, developing the diagnostic and the presentation software.

Where is this today? Some life underwriters are using this in a production mode today. My company is in early trials with individual and small group health underwriters on a pilot basis.

PREDICTIVE MODELS

The second tool I want to tell you about is prescription-based predictive models. The idea here is a software model that takes year-one pharmacy claims and makes a forecast about year 2 total medical claims on an individual. If I know the prescription record in a year, then I'm going to make a forecast about their total medical costs in year 2.

Several companies have developed these kinds of models, these pharmacy-based predictive models, over the past few years. By and large, these companies have focused their development on the risk adjustment or reimbursement settings in managed care. It's only recently that we've taken a look at using these models in an underwriting mode.

Model Design. Here's how these models generally are designed: The input to the model is pharmacy claims. The model will group National Drug Codes (NDCs) into categories, typically categories based on pharmacy-based categories or disease categories or a combination of those. And then attached to each category is a weight or a score. Then for an individual, you add up the categories, add up the scores, and come up with a predictive score for next year's medical claims.

Some models use additional indirect factors like the number of prescribing physicians or utilization trends. For example, if we know that a prescription drug has been intensively used over the past few months, that might weight more than if that same drug had been used 12 months ago. So utilization trends can affect the score in some models. It's a relatively simple design, an additive model based on categorizing NDC codes.

How good are the models? Well, just this month the Society released a risk adjuster study that analyzed these and some other kinds of models. In general, the pharmacy-based models were compared to diagnosis-based models—models that took diagnosis in and made a prediction about total cost in year 2. The pharmacy-based model did very well, often bettering the results of the diagnosis-based models.

Another indicator of where predictive models are today is that major health insurers are beginning to use pharmacy-based models in their underwriting process today.

How Tools Are Used in Underwriting. I want to describe how these tools can be used in the underwriting process. I'm a health actuary, so I base this on health underwriting, but it really can apply to any kind of underwriting, such as life or disability, in which your goal is to ascertain the health status of an individual applying for insurance.

The typical current approach starts with the application. You ask an individual health questions on the application and then verify health information from the individual by outside data—either an attending physician's statement (APS), a Medical Information Bureau (MIB) report, or a phone interview.

Once the verification or investigation is complete, then the underwriter makes some determinations on the condition or health status of the individual and makes an underwriting decision. That can be an accept-decline decision or a rating decision.

The underwriter uses his or her own judgment, experience and expertise, as well as the company's underwriting guidelines and possibly underwriting software.

These two new pharmacy-based approaches can enhance this approach by supplementing or replacing certain steps. For example, after the individual fills out the health questions on the application, you can order the online prescription history. Again, this is something that happens in minutes versus the attending physician's statement, which can take 30–90 days. So the online pharmacy history is real-time right now, which can greatly speed up the underwriting decision-making process.

Once you have the prescription history, the software that I talked about can infer a diagnosis and help the underwriter make a medical determination. Then you can plug that into a pharmacy-based predictive model to assign a risk score on that individual. So all these steps can be automated. The online prescription history can be obtained automatically. It can be fed into the diagnosis engine and then fed into the predictive model, ending up with a risk score on the individual.

Now, it's probably not in a state where you want to go out with that risk score that pops out of the machine, but it's very much a useful tool for the underwriter. It will allow the underwriter to focus on the difficult pieces, the difficult cases, whereas this approach can largely be automated on the more routine cases.

BENEFITS

There are several benefits to using this approach.

Third-Party Verification. First of all, for the first time, there's third-party, real-time verification of the application. So, for example, if Jane Doe forgets to put down on the application that she has asthma, it's likely that the pharmacy record will prove that out. Here's a way, in real time, to verify what's on the application.

Because the diagnosis software can aid the underwriter in pinpointing a more accurate diagnosis other than using just the data on the application, it can result in more accurate rating. And the process certainly can be sped up. As I said, attending physician statements take 30, 60, 90 days to approve. This is a real-time or a near-real-time kind of an approach.

More Sales. Faster underwriting decisions will lead to more sales. You can issue a policy to someone who, under a previous approach, might have been waiting for the underwriter who was waiting for the attending physician's statement. Now you issue the policy and close the sale.

Customer Friendliness. In addition, having a faster underwriting process is more customer-friendly, and you're going to attract and retain agents more effectively with a process that aids the consumer. Agents like processes that are consumer-friendly.

Because all this can be automated, it can lead to the development of instant issue products. Knowing the pharmacy history allows you to make some underwriting judgments via software or in real time.

EXAMPLE FOR USE

Here's an example of applying these tools to renewal underwriting, and here I'm thinking of small group health underwriting where you're renewing a group every year.

Currently you review the total medical claims experience of the renewing group. Either the underwriter or software will mark red flags—conditions or loss ratios that stand out and indicate follow-up. Then the underwriter will determine the medical condition and make a rating decision.

Using these tools, you can have a slightly different approach, and that's to take the prescription claims only (not all the health claims), send the prescription claim through the predictive model, have the predictive model identify medical conditions and red flags, and determine an individual risk score. I should point out that red flags or conditions to be aware of can be spotted only through the prescription record.

There are conditions for which you might not have seen claims come through yet, either because there's a lag in the standard claim process or claims haven't been submitted yet. Whereas what drug the individual is taking can tip you off to a condition.

So the model can identify red flags and determine an individual risk score. You can aggregate the individual risk scores into a group score for the small group and then turn that into a rating for the small group. So now the software spits out a rate for the group allowing the underwriter to make a review and final judgment and allowing the underwriter to focus on the more difficult or the special cases, letting the software crank through on the more routine cases.

The benefits stem from the quality and timeliness of pharmacy data. With pharmacy data, as you know, there's little or no lag. Typically, health plans are

getting weekly, if not daily, claims back from the PBM; so there's little or no lag, as opposed to a standard health claim where there are weeks or months of lag.

And the coding is much simpler on pharmacy data. That's really what allows these predictive models to work—standard, simplified coding that is followed throughout the industry and that allows the predicative model to work.

The process also can provide for a more uniform underwriting rating approach. Because it's software-based, it won't matter whether the case goes to your most experienced underwriter or your newest underwriter. The process will be much more uniform, both rating and underwriting. And, as I mentioned, it will allow the underwriter to focus on special or more difficult cases.

CONSIDERATIONS

If you're thinking of getting into these two tools, there are some considerations to look at when you're choosing a vendor.

First of all, raw pharmacy data from the PBMs may be difficult for the underwriters to interpret. You don't want to flood the underwriters with tons of raw PBM data. You want software that can make sense of that for the underwriter.

Another consideration is that your underwriting process may be unique. Be careful of cookie-cutter approaches that may not fit with your workflow requirements. Choose a vendor that can know and understand your underwriting process, your underwriting guidelines, and customize the software to work with your process. And pick one that can integrate the Rx history and the risk scoring to convert this to usable information for the underwriter.

In summary, these two new approaches, I think, are pretty exciting and can result in significant competitive advantages: rapid turnaround, outside verification of applications, more accurate rating, better risk selection and more uniform underwriting, which can lead to increased sales and greater profitability.

MS. JILL VAN DEN BOS: I'm with the Denver office of Milliman and work in the health practice there. A few years ago, we stumbled across an article in *Health Affairs* decrying the gap in communication between the pharmaceutical industry and the managed care organization (MCO) industry and discussing the notion of pharmacoeconomics (PE). We became interested and looked into it.

This is a definition of PE, a somewhat general definition: PE more specifically has to do with studies of drugs and their consequent costs or quality of life associated with drugs in the market. This is from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) lexicon.

PE research typically is sponsored by pharmaceutical companies. The research may be done by professors at a university, by people in the company or by independent

companies, but the pharmaceutical companies typically pay for this. And they're doing it usually in the promotion of a new drug that's in testing right now.

Up until now, PE research often has been almost a side effect of doing FDA clinical testing. When they're getting into phase 3 and they're getting ready to think about marketing this stuff to the MCOs, they say, "Let's throw in some economic measures and get this information so that we can turn around and please the formulary committee when we go to apply."

Most of these studies compare one drug against the top competitor or against the placebo. They don't typically look at a broad range of treatments for a condition. And again, most of this stuff is done in preparation for the dossier that is submitted to pharmacy committees when they're looking to add new drugs to the formulary.

PE LITERATURE

PE literature is sort of a new literature, and it's fraught with problems, like many of them are. This one's still maybe getting its sea legs more than some other areas of research. Some of the problems are typical of other areas of research, as well, but this one is particularly fraught with four problems.

Small Sample Sizes. When studying a clinical aspect of research of a new drug, for example, very often you're looking at a binomial thing. It either is or it isn't. It works or it doesn't. When you go on to study the cost consequences or side effects of drugs that are pretty infrequent events, you need a much bigger sample size, and they just don't get them.

I saw one study when we were looking in the literature at one particular condition. The target drug had a sample size of six, and the comparative drug had a sample size of 10. And when they measured the cost for the two, there had been a hospitalization due to a side effect in the comparative drug case, and that cost overwhelmed the total cost of everything else. Therefore, the author concluded that the target drug was much less expensive than the comparative drug based on that tiny sample. And that was published. So that's an example of why the literature needs to get its act together a little bit.

Publication Bias. Publication bias is typical in any area of drug research, I'm sure; but, again, it comes up in this area as the pharmaceutical company is sponsoring the research, and the research doesn't show that their new drug is the better drug or at least as good as the other drug or whatever. That study goes in the round file and never sees the light of day. So what you look at when you see the literature is a biased sample of what possibly really happened.

Sponsorship Bias. Sponsorship bias is a real problem in this area. It's an actual problem and also a perceived problem, to the extent that pharmaceutical companies are always the ones that are paying for the research done on their own drugs. They want certain results, and they may or may not exert pressure to get

these certain results; but the perception that they do is clearly there and colors any use of the information that may be made by their target audience. They also do actually seem to apply some real pressure.

I saw a review article in which something like 39 articles talking about nonsteroidal anti-inflammatory drugs were reviewed. And in 95 percent of the cases or something like that, the target drug was found to be superior or great or nontoxic or whatever they were looking at.

In a subsample of those studies, there were 19, I think, that were studied for toxicity. In all cases the author said the target drug was less toxic than the other drug or no more toxic than the other drug; however, the research backing it up right there in the very article didn't back it up all the time. In only 12 cases was the conclusion determined to be justified. So you have to read carefully when you're looking at research that's sponsored by somebody with an interest.

Finally, many of these studies are not transparent—meaning they're not good about disclosing the methods that they use to measure things or about telling you everything that they even measured. If they're talking about cost, they didn't specify what comprised those costs. Or, in the case of some stuff we were looking at, if they said, "Yes, the ulcer rate was such and so," they didn't say how they measured it. So you have to pick and choose among the literature if you're going to use this stuff for anything substantive.

Up until now, PE research has tended to be overlooked by MCO actuaries. Many problems, as already stated, make the literature hard to deal with. Also, this field has been put together by economists. It's still coming about and is very new, but it looks very academic when you look at the research. It doesn't tend to look business-oriented, which is what people and the MCO want to see. They're running a business. So it's hard to make use of some of the articles when they're talking about dominance theory or some other sort of economic result. It's difficult to decide how to use that information.

FORMULARY FORMAT

The Academy for Managed Care Pharmacies recently—about a year and a half ago, I would say—put out a format for formulary submissions. This is a set of guidelines for pharmaceutical companies to use when they're preparing a dossier to submit to a MCO to try to get the new drug on the formulary. This format is a template or a guide. It's not a mandate, but it does try and codify, to some extent, what you need to be describing about new drugs when you want to get yourself out there in the market.

It concentrates on five areas, the first being a description of the disease and the agent's role in treating the disease. Number two is the clinical efficacy, safety, effectiveness—typical clinical trial stuff.

Number three is economic evaluations. I mentioned that, up until now, these have sometimes been treated as an afterthought. Now, they're saying, "Put this in here, make it important, make it one of your five points."

Number four is modeling, and number five is clinical value.

CHANCE TO IMPROVE QUALITY

We suspect that the advent of the format for formulary submissions will lead to an improved quality and quantity of research out there now that everybody has got to put something together—some sort of PE information together on their dossier preparation. Whereas they may or may not have done it before or did it haphazardly, now they need to concentrate on it and do a good job, in theory, if other people are going to be looking at it and comparing it. So hopefully, that will lead to an improvement of standards.

We think that PE research would do well to find a broader audience within an MCO. Up until now, people have been aiming this stuff toward a PNT committee. They want to get on the formulary. That's all they're thinking about; however, other people within the MCO audience may be interested in the information and in fact could be interested in the information.

We feel that the field could be much improved by the addition of actuaries—imagine that—to help make the information more useful to MCOs. The economists don't speak the lingo, if you want to put it that way, and don't put together what I would consider practical results in many instances. They're more academic-looking results. And if somebody is going to use this information, their target audience is the MCO. If they want the MCO people to use this information, we think maybe they ought to rethink how they put it together.

Also, if they try to appeal to other people within the MCO other than simply the formulary committee, I think they might be pleasantly surprised. People in the pharmacy division very often are responsible for their own budget and nothing else.

You'll find representatives of pharmaceutical companies complaining that people in the MCOs only care about cost per pill, and they don't care about anything else. Well, if you're talking to a person whose portion of the budget is this, rather than an actuary or somebody who's responsible for the entire budget, the entire bottom line, you're going to continue to run into that attitude. So broadening their audience would serve them as well.

PE research is often a side effect of clinical trials right now, but if it could be gathering this information and combining it with claims data and clinical research, particularly the claims data piece, it really could prove to be much more useful. We could look at medical cost offsets in other areas and get the pharmacy budget out of the silo, so to speak.

f we can broaden the audience within an MCO, I think you'll find that the data become useful not only to the PNT committee, but actuaries and, potentially, utilization management people for benchmarking. Executive management, theoretically, should be interested in all of this stuff.

ARTHRITIS SAMPLE STUDY

We did a sample, I guess you'd call it a sample study on arthritis. To do this study, we wanted to sort of demonstrate what we thought an actuary might add to a PE viewpoint.

So we looked for published research on osteoarthritis. We went and compared treatments for osteoarthritis, all treatments for osteoarthritis, rather than picking one and a comparator, or a comparator and a placebo, or whatever you typically find in the literature.

Rather than focusing on all possible treatments of osteoarthritis, we narrowed it down to NSAIDs, which doesn't narrow it much, as it turns out. I mean, some people with osteoarthritis are treated with steroids or slow-acting antirheumatic drugs or other things, but it's not as common. Most of them are treated with NSAIDs, so we focused on that.

It turned out to be a good place to focus because NSAIDs are somewhat easy to study, in this respect, because the literature generally suggests that they have roughly equivalent efficacy. No one stands out as better than the other to the population in general. What does differentiate them is the quantity of side effects—some are more toxic than others, if you want to put it that way. So this became really a study of toxic side effects, assuming efficacy was roughly the same down the line.

We combined information from the PE studies and the literature, clinical studies in the literature, and cost of drugs. And we had access to a proprietary drug frequency database from one of our large pharmaceutical company clients that we were able to bring in on this. I should note that this research was done prior to the COX-2 inhibitors coming onto the market, which would, of course, change everything. They're very popular and used very much in the market right now.

The Decision Tree. What we did was make a decision tree. For each person treated for a condition, we considered the probability of various outcomes and made paths, with probabilities associated with each path and a cost associated with each of those paths.

Using the cost of the paths and the probability of going down the various paths along with the cost of the drug, we estimated the total cost associated with each of these treatment options.

This demonstrates the awesome nature of the research that we put together (Chart 8). It has a whole panoply of drug options down the side, then little paths for each one. It has the fingers of the tree, and then it has costs and probabilities associated with each one.

This is one of those branches for a drug called Nabumetone, which is relatively nontoxic in the scheme of things (Chart 9). We start with the drug name and a few cost items. The cost for a three-month supply of Nabumetone is $183.96.

Then you go to the choice points, and you have ulcer and no ulcer—0.8 percent probability of getting an ulcer on this drug. If you get the ulcer, then you have an 8.6 percent chance of being hospitalized versus the rest being treated with ambulatory treatment. And finally, hospitalized people have a 12 percent chance of having surgery versus no surgery.

If you go down the bottom path, these are people who do not get ulcers—9.3 percent of them get other G.I. problems, the rest are not treated for anything. The percentages in the second to the right column represent the percentage probability of ending up at that point on the path, and the costs next to those are the estimated costs of going down each of those paths.

If you take the sum product of those two values and then add them to the cost of the drug, you end up with this value all the way over to the left. The $217.55 is the estimated cost for treating a population with this drug for three months.

This is a parallel case (Chart 10). I just picked one that's much more toxic. You can see that Ketoprofen has a 28 percent ulcer rate, and then the rest of the top portion of the tree has the same percentages.

If you go down to the bottom percent of the tree, you don't get an ulcer. More than half of you will end up with some other G.I. problem for which you were treated. You can see that the cost of the drug in this case, the $220.32, is not terribly different than the cost of Nabumetone, but the total cost of the drug treatment all the way to the right, $650.86, is much, much higher, mostly attributable to treating side effects caused by using this drug.

This is an estimate of current drug costs (Table 1). We used the Medicare population. We also did a commercial. I just presented the current cost of Medicare treatment using these data.

Table 1

Current Medicare Costs

Estimated Current Cost of OA Drugs for Medicare Enrollees			
Treatment	Rate of Use	Cost per month	Cost PMPM
Acetaminophen	0.000%	$0.00	$0.00
Ibuprofen	0.515%	$66.65	$0.34
Nabumetone	0.000%	$72.52	$0.00
Piroxicam Gel	0.155%	$74.58	$0.12
Indomethacin	1.573%	$98.57	$1.55
Naproxen	5.949%	$109.14	$6.49
Piroxicam	0.470%	$114.52	$0.54
Ibuprofen+Misoprostol	0.031%	$126.35	$0.04
Diclofenac	3.264%	$129.39	$4.22
Fenoprofen	0.155%	$134.99	$0.21
Naproxen+Helidac	0.005%	$136.02	$0.01
Sulindac	0.957%	$144.83	$1.39
Aspirin	1.546%	$152.34	$2.35
Etodolac	0.069%	$161.30	$0.11
Diclofenac+Misoprostol	0.094%	$194.33	$0.18
Flurbiprofen	0.587%	$216.66	$1.27
Ketoprofen	0.98%	$216.95	$0.21
TOTAL	15.465%		$19.03

We got the rate of use column from our proprietary drug database. You'll notice we have no use under acetaminophen, because it's an over-the-counter drug, and we wouldn't know that going in; so we just dropped it in there, and we'll use it going forward. At any rate, the second column has costs for the drugs, and then the total PMPM includes the cost rate for the number of people given the cost of the drugs and the cost of treating the side effects from taking those drugs.

This table shows cost after intervention (Table 2). We assumed that you put in place some sort of protocol, trying to get physicians to move up the list and prescribe up the list—step-up therapy, possibly, using Grady's term, and trying to start at the top of this list and get people to try these drugs in this order, the least expensive, the least toxic order.

Table 2

Medicare Costs After Intervention

Estimated cost of OA Drugs for Medicare Enrollees, Following Intervention			
Treatment	Rate of Use	Cost per month	Cost PMPM
Acetaminophen	1.551%	–	--
Ibuprofen	1.551%	$66.65	$1.03
Nabumetone	1.551%	$72.52	$1.12
Piroxicam Gel	0.776%	$74.58	$0.58
Indomethacin	2.017%	$98.57	$1.99
Naproxen	3.723%	$109.14	$4.06
Piroxicam	0.310%	$114.52	$0.36
Ibuprofen+Misoprostol	0.620%	$126.35	$0.78
Diclofenac	1.551%	$129.39	$2.01
Fenoprofen	0.155%	$134.99	$0.21
Naproxen+Helidac	0.310%	$136.02	$0.42
Sulindac	0.465%	$144.83	$0.67
Aspirin	0.465%	$152.34	$0.71
Etodolac	0.031%	$161.30	$0.05
Diclofenac+Misoprostol	0.155%	$194.33	$0.30
Flurbiprofen	0.155%	$216.66	$0.34
Ketoprofen	0.078%	$216.95	$0.17
TOTAL	15.465%		$14.80

The rate of use in this case was estimated, just based on the question, "What if we could get this distribution after treatment intervention—intervention with the prescribing doctors, actually?" That's something you would have to work out with somebody who's in the know for your population in particular, but we just thought, "Well, people who are on a particular regimen will probably stay on that regimen; maybe they'll move to a new one. We'll try to move them up this list. New people, we'll try and start them at the top of the list and move them on down."

You'll also notice in the second column that the cost per month has no cost for acetaminophen. This cost per month is from the perspective of the MCO, and acetaminophen will never have a cost for them, since it's over the counter. It's a good place to start, because it's the least toxic of the bunch. It doesn't have many bad side effects.

And finally, you'll see the PMPM on the bottom is a little bit more than $4 different from the prior one. This could be substantial—NSAIDs are really used a lot. In the Medicare population, everybody has arthritis. Supposedly every animal with bones eventually gets arthritis, I think I read. So that's an area where there's a lot of potential for cost savings.

In conclusion, I think combining information from the various sources and putting together a study possibly similar to the one that we did or something else using

claim cost from across the areas of treatment within an MCO can provide a very interesting study.

It's something that gets you a little bit outside of that tendency to look at pharmacy costs only in the pharmacy budget and not look at the pharmacy costs that happened elsewhere or pharmacy savings that happened elsewhere when, in fact, that may be where the biggest dollars occur—the biggest savings or biggest additional dollars needed to treat side effects of various drugs.

You can look at the cost impacts for making these changes across the total health care budget, which is much more useful in the long run than simply parsing out your budget and looking at different pieces independently.

And finally, if you do a study like this, we can do one that states the results in terms of PMPM claim costs, which is language we all understand. It's information that we can use, and it makes the PE information more useful and useable for the target audience, which is the MCO.

MS. WEAR: We have about 10 minutes, so now I would be happy to take questions.

MR. ROBERT LYNCH: Grady mentioned the direct-to-patient marketing by drug makers and pharmacists, sending letters to patients to basically hint that they switch drugs. And a question that immediately popped up in my mind is of a conflict with HIPAA confidentiality requirements. This is putting out potentially confidential medical information. Is there a loophole that the pharmacy lobby put in there?

MR. CATTERALL: This was actually the focus of the article about the pharmacists' letters, that it probably was, at least in moral terms, a violation of privacy, and possibly in legal terms as well.

And one particular instance involves AIDS patients receiving these mailings. One AIDS patient was particularly upset, because he was in a building where there were a lot of mailboxes lined up, and people often got the wrong mail. And so it was publicized as something that he thought should not be publicized. It is a big problem, and there are questions about the legality of that as far as the morals of it.

FROM THE FLOOR: In the area of cost pressures for drugs, I've heard very little about any effects of the globalization of the economies and, for example, perhaps generic drugs from India or things along those lines. Is there any part of the overall global picture that will be affecting the cost pressures on pharmacies?

MR. CATTERALL: I think there's a potential for increasing globalization putting some downward pressure on prices. As we have more unrestricted free trade, it

might become either more difficult or nations might be less inclined to stop the flow of prescription drugs across borders.

Right now, we have seniors taking bus trips to Canada to get cheaper prescription drugs there. Congress—I can't remember if it was actually enacted or if it was being opposed—but there was some proposal to remove the restrictions on importing prescription drugs, at least for personal use.

But drug manufacturers say, "We can't allow the importation of drugs from places where they're cheaper because there are safety issues." My response is that it depends on where they're coming from. You know, I'm not concerned about safety issues from Canadian drugs. It could be a problem from some other countries.

FROM THE FLOOR: Do they still pretty much have the upper hand in the politics of that environment?

MR. CATTERALL: I think there's a backlash right now. It happens every few years—there's a backlash against pharmaceutical companies. And a lot of times they respond to that, even if no legislation has passed.

For example, the Clinton Health Care Plan wasn't passed, but during that time, there was a moderation of pharmaceutical price increases, because the pharmaceutical manufacturers knew they had to regain some public goodwill.

MR. GREGORY DAVIS: I have a couple of questions or comments maybe regarding using prescription data in predictive modeling. I think of credit scores now that are used by credit bureaus to rate your credit for getting a loan or something. And so I think of some issues: What if there's information on there: can a person applying for insurance look at that information? What access do they have to that? How far do you go back in looking at those data?

What if the doctor prescribes the wrong medication for you? How would that affect you? Can you go back and have something changed or, you know, what kind of issues are there, and what might be done about it?

MR. FRANZEN: You raise a great point. In fact, those very issues that you bring up are coming to the fore much like in credit reporting.

This is a very new concept, and it's just now being piloted. But in answer to one of your questions, if an underwriter makes a negative decision on a decline, for example, then we'll have to give information about why that decision was made, including the prescription history that allowed us to make that decision. So then, much like a credit report, the individual would have a chance to challenge that.

MR. DAVIS: I guess the only other thing I might add is, could there be ways to game the system, where maybe there are alternative drugs for treatment? And

maybe an alternative could be for something that's much more serious. So maybe you as a consumer might want to use certain drugs to increase your chance of getting cheaper insurance in the future.

UNIDENTIFIED SPEAKER: I would think there would be more ways to game the system. Don't use your insured benefit.

MR. DAVIS: Well, exactly.

UNIDENTIFIED SPEAKER: Pay cash at the pharmacy.

MR. FRANZEN: Yes, I think there are conceivable ways to game the system. I would say that, again, as this becomes more prevalent, we'll start to see some of those issues. Just like in any underwriting or risk selection process, you have to put up the proper defenses.

MR. MARTIN HILL: On the same topic, I've just got a question on the cases. You'd mentioned that the process starts with permission from the individual to get their drug history. In the case where they refuse that permission, my question is, How do you handle those cases? Do you have a load of 40 percent or something on the average? Do you refuse to insure them? And what legal restrictions are there on what you're allowed to do in those cases?

MR. FRANZEN: Yes, I think much like in current underwriting situations in which you want permission to be able to go ask their doctor for their medical records, you're going to make that part of the application. So if you don't sign every part of the application, you're not eligible, your application is denied.

And so, again, the insurer has a right to know things that the individual knows, and that's the whole idea here—make it part of the application that you get. The individual gives permission to go after that information.

MS. AUDREY HALVORSON: Jill, PE analysis is cool. I got an opportunity to go to the AMCP conference up in Vancouver about a year ago. I was invited by our PNT committee, and they were a little bit afraid of having an actuary there.

But I had the great opportunity to look at this PE analysis that they give to the PNT committees, and you're right. It's clinically based, with maybe some economics. And it's very difficult to translate into something. And I'm wondering: From your perspective, are you working with anybody, with the AMCP, to maybe change that brand new form that they have to make it more useful for MCOs to look at? Or what do you think is the opportunity for actuaries to get involved?

MS. VAN DEN BOS: Yes, we're going to work on them next. First, I'm working on ISPOR, which is the International Society for Pharmacoeconomics and Outcomes Research. They put together several special interest groups this year including one

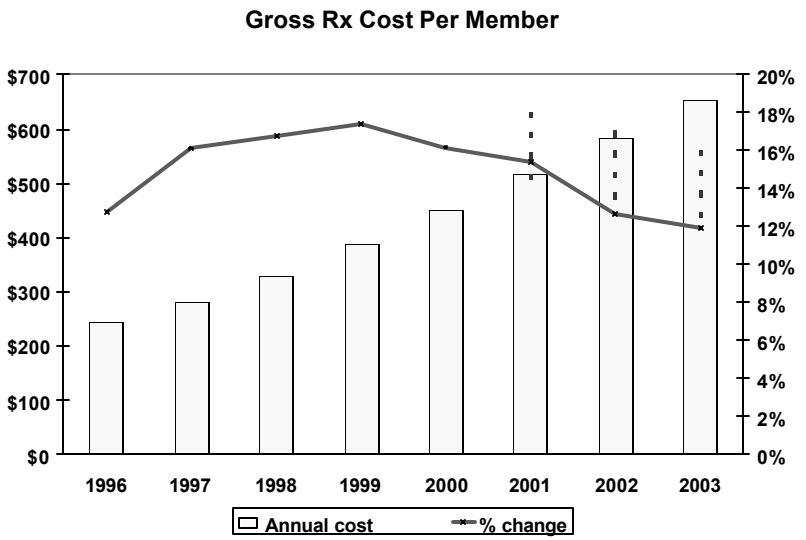
to address just this issue: How do we connect the gap between the pharmaceutical industry and managed care?

They sent out a survey and said, "Who wants to be part of this, and does anybody have any comments?" And I gave them some comments, and everybody, when I went to the meeting, said, "Oh, so you're the actuary." So evidently, they passed it all around. This was all news to them. So that's one place to start.

Also, yes, some folks from our office are hoping to speak at the AMCP. And we also have been trying to come up with some draft guidelines for what we think an actuarial certification, if you want to put it that way, of a pharmaceutical dossier might look like. And we hope to disseminate some of these ideas in the near future.

Chart 1

Pharmacy Cost Increases: Recent History



Sources: Express Scripts *2000 Drug Trend Report*; Merck-Medco *Drug Trend Report 2001*

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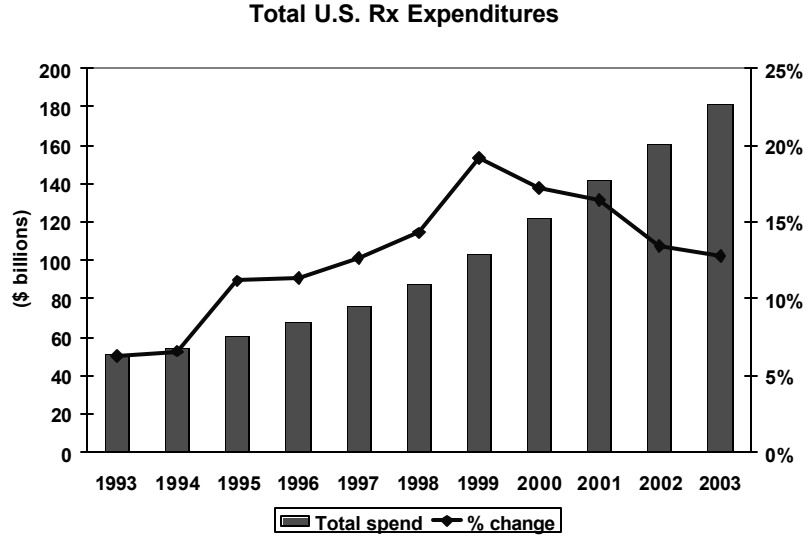
Chart 2

Pharmacy Cost Increases: Recent History



Sources: CMS; AdvancePCS

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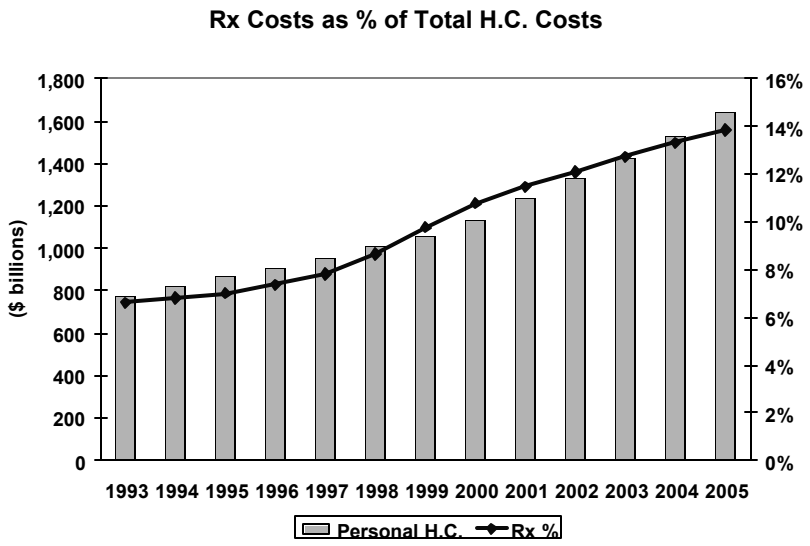
Chart 3

Pharmacy Cost Increases: Recent History



Sources: CMS; AdvancePCS

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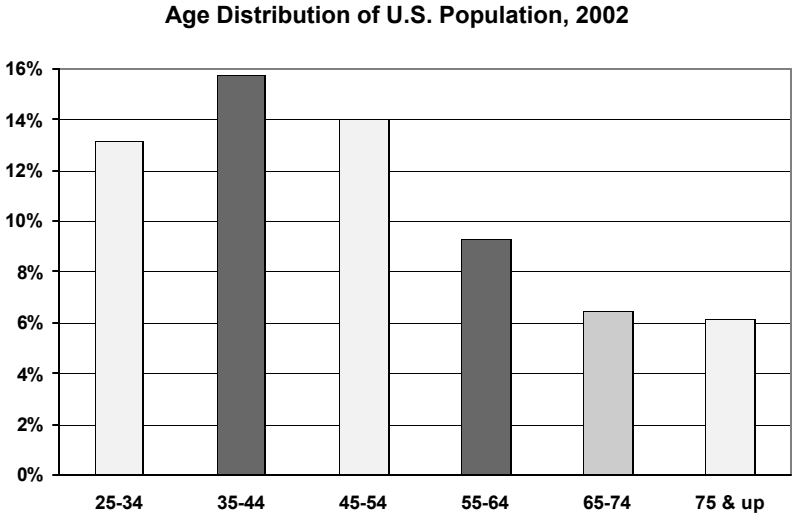
Chart 4

Pharmacy Cost Increases: Underlying Causes

A. Aging Population



Source: U.S. Census Bureau

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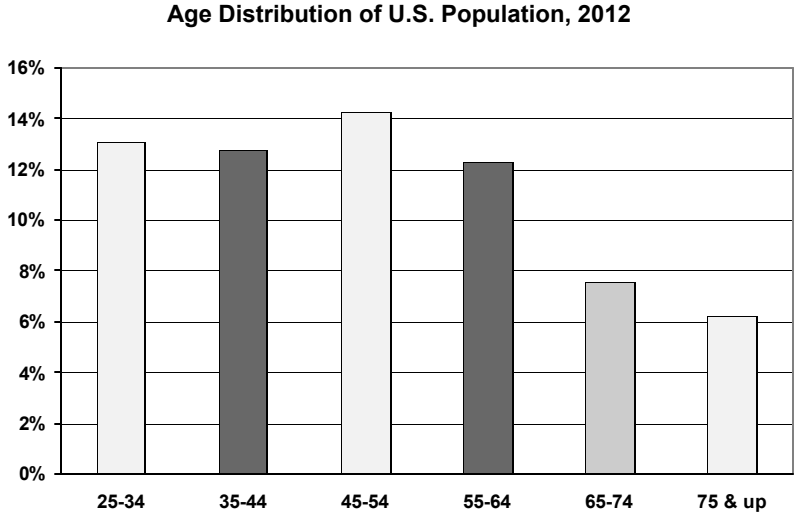
Chart 5

Pharmacy Cost Increases: Underlying Causes

A. Aging Population



Source: U.S. Census Bureau

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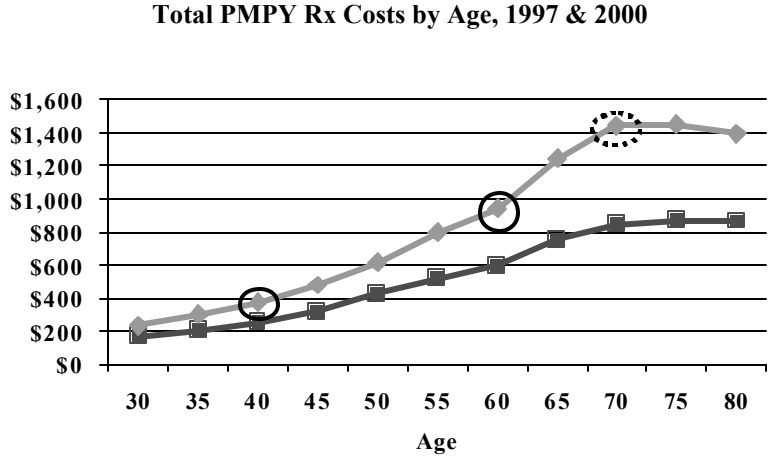
Chart 6

Pharmacy Cost Increases: Underlying Causes

A. Aging Population



Sources: Schneider Institute; AdvancePCS

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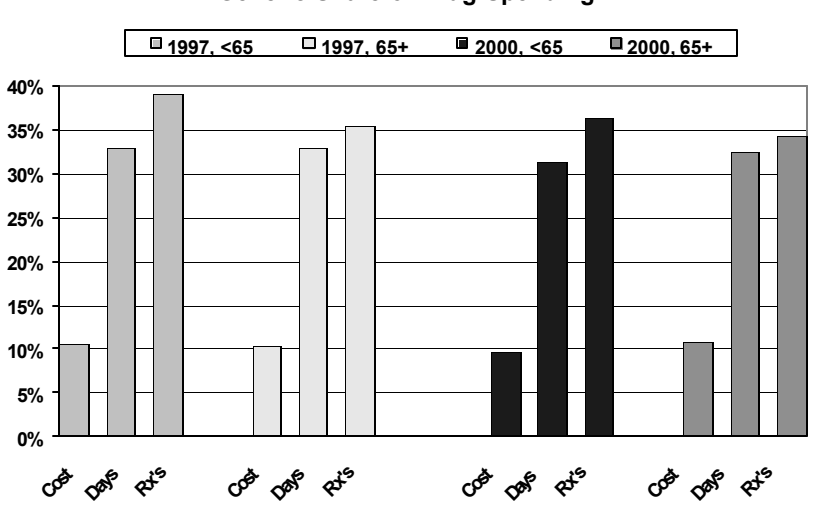
Chart 7

Pharmacy Cost Increases: Underlying Causes

D. Thwarting Generic Competition



Sources: Schneider Institute; AdvancePCS

Chart 8

Total Treatment Costs for a 3-Month Period Using Mean Ulcer Rates

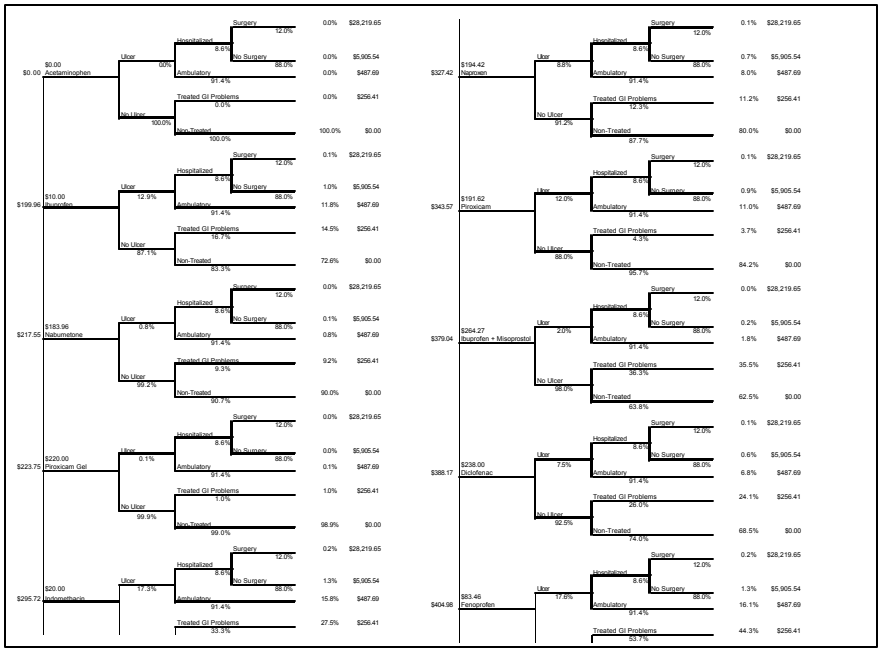


Chart 9

Total Treatment Costs for a 3-Month Period Using Mean Ulcer Rates

Nabumetone

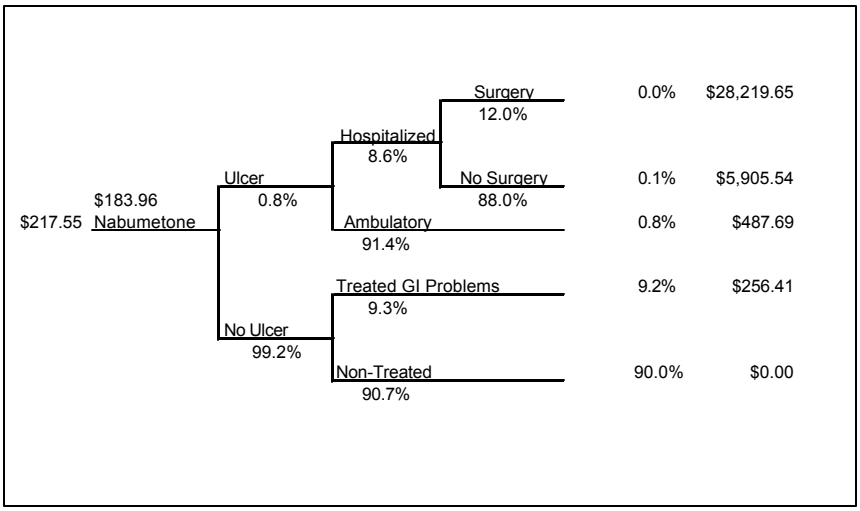


Chart 10

Total Treatment Costs for a 3-Month Period Using Mean Ulcer Rates

Ketoprofen