AIS’s Management Insight Series

Copay Coupons for Specialty Drugs: Strategies for Health Plans and PBMs

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Introduction

As the biologics pipeline continues to grow and patients face increasing specialty copays, co-insurance and maximum out-of-pocket limits, manufacturer-offered specialty drug coupons are becoming more commonplace. And with biosimilars soon entering the market, it will be critical for payers to identify quickly and combat coupon programs that are damaging to their efforts to manage specialty drugs. Keeping abreast of coupon redemption and additions to therapy in specialty categories like multiple sclerosis and rheumatoid arthritis, which have become rich with therapeutic options, will be especially important as those categories experience high copay offset utilization. *Copay Coupons for Specialty Drugs: Strategies for Health Plans and PBMs* provides details of steps health plans and PBMs are taking to manage the rising use of consumer copay coupons in specialty pharmacy.

Health plans and PBMs generally agree that copay coupons offered by makers of traditional brand-name drugs circumvent formulary compliance ... and have utilized various strategies designed to offset their use. But when it comes to coupons and discount programs associated with high-cost specialty drugs — where there are considerably more dollars at stake — many payers are taking a more selective, nuanced approach, since coupons may improve adherence to potentially unaffordable treatments.

*Copay Coupons for Specialty Drugs: Strategies for Health Plans and PBMs* discusses the details of strategies payers can employ to manage specialty drug coupons without compromising patient access. This report offers information on:

- The differences between copay coupons and patient assistance programs, and the ways they are being marketed by biologics manufacturers.
- Which specialty drug coupons may be undermining your formulary efforts and which programs may be impacting medication adherence.
- How to track and manage the use of specialty drug coupons through your preferred specialty pharmacy or network of pharmacies.
- Evaluating formulary and utilization management strategies to ensure that patients and physicians have access to clinically appropriate, cost-effective therapies.
- Understanding the changing strategies of biologics manufacturers as they compete to maintain their market share of therapies.
- Learning the pros and cons of a number of strategies that can be used to combat the use of specialty drug coupons.

The report was updated and adapted from a June 5, 2014, webinar sponsored by Atlantic Information Services, Inc. Attendees at the webinar, “Health Plan/PBM Strategies to Manage Specialty Drug Coupon Programs,” got the chance to have their toughest questions answered by the following experts:

- Alaina Sandhu, consultant for the National Pharmacy Practice at Buck Consultants, LLC; and
Steven Avey, vice-president of specialty programs from Medimpact Healthcare Systems, Inc.

*Copay Coupons for Specialty Drugs: Strategies for Health Plans and PBMs* also includes questions posed by the webinar attendees and answers provided by the speakers.

And appendices filled with relevant background coverage of industry developments, federal agencies’ guidance and preparatory materials and other resources give you the tools to manage the use of specialty copay coupons. They include:

- **Appendix A:** A collection of articles tracking developments on copay coupons from AIS’s leading health business newsletters, including *Specialty Pharmacy News* and *Drug Benefit News*.
- **Appendix B:** “Zitter Health Insights’ Co-Pay Offset Monitor,” a report prepared for AIS showing copay program utilization data and trends.
- **Appendix C:** “Prime Position: Manufacturer Copayment Coupons,” an August 2014 paper from Prime Therapeutics on copay coupons.
- **Appendix D:** HHS and CMS Guidance on Qualified Health Plans (QHPs), including a letter to Rep. Jim McDermott (D-Wash.) from HHS Sec. Kathleen Sebelius and a CMS Center for Consumer Information and Insurance Oversight answer to a frequently asked question. Both documents relate to the use of copay coupons on exchanges.
- **Appendix E:** HHS and CMS Guidance on Patient Assistance Programs (PAPs), including an HHS advisory bulletin and CMS perspectives on patient assistance programs.

Erin Trompeter
Managing Editor
Atlantic Information Services, Inc.
Specialty Copay Coupons: Higher Stakes

Copay coupons are manufacturer-sponsored programs for patients with commercial insurance coverage. Because of anti-kickback statutes, coupons cannot be used on Medicare, Medicaid, TRICARE, The Department of Defense or Veterans Affairs programs or where prohibited by law. By contrast, patient assistance programs (PAPs) offer free or low-cost drugs to primarily uninsured patients who are financially eligible.

Most drug couponing programs have been geared toward non-specialty or traditional drugs. Insurers and pharmacy benefit managers (PBMs) believe these coupons generally undermine their health plan formularies and employer cost-sharing strategies because when patients use coupons to obtain brand-name medications, their own out-of-pocket expense is reduced, taking away the incentive to use a lower formulary-tier or generic medication.

Copay coupons do not change the medication’s true cost; as a result, payer spend may be higher because the patient is choosing a higher-cost product.

However, when it comes to coupons and discount programs associated with high-cost specialty drugs, many payers take a more cautious approach, since coupons may improve adherence to potentially unaffordable treatments, thus reducing overall medical costs.

The specialty pharmacy space has received increased scrutiny because of rising drug costs and the number of new drugs – about 900 – currently in the pipeline.

Seven to 10 of the top drugs by revenue will be considered specialty in 2016, up from about five in 2012. Trend increased 15% to 17% in 2012, 19% to 20% in 2013, and then in 2014, an increase of 22% to 25% is predicted.

The following four factors contribute to these changes:

◆ **No set definition for specialty drugs.** Although there is no standard definition for what constitutes a specialty drug, these drugs often are produced using recombinant DNA technology or require specialist expertise, handling or counseling.

◆ **Booming market.** Eight out of 10 drugs approved by the FDA in the next five years are expected to be considered specialty drugs. Biosimilars are not expected to produce the same price decrease as non-specialty generic drugs have.

◆ **Increasing utilization.** Utilization of specialty drugs is currently low – 1-2% – with respect to the total population but is expected to increase 10% or more in that next few years mainly because of new drugs, increased specialty drug use as first-line therapy and new indications for these specialty medications.

◆ **Increasing specialty drug spend and costs.** Specialty drug spend typically accounts for 12-30% of total drug spend and is predicted to increase to 40-50% by 2020. The average cost for a specialty patient is about $2,000 per month.

Prescription drug coupon programs have seen significant growth over the last few years. From 2012 to 2014, the numbers have jumped from 400 to more than 550 drug
couponing programs. Specialty prescriptions have seen a particular increase in growth because of the increasing drug pipeline. Specialty coupon program availability varies widely by the therapeutic class. Because rheumatoid arthritis and multiple sclerosis are classes that have more readily available generic substitutes, they see more programs and greater use or availability and marketing efforts.

Plan sponsors do fear that use of specialty coupons might undermine their strategies with regard to formulary development, rebates or cost-share. Payers want to drive use of preferred brands to maximize rebates, for example, or drive lower cost alternatives. The use of coupons takes away the member’s incentive with regard to the plan design’s cost-share arrangement.

Specialty coupons can also help members, who are typically sensitive to the high cost-share of specialty drugs, especially with the prevalence of fourth-tier plan designs and the increasing use of high-deductible health plans. Members whose conditions require high-cost specialty medications are those hit hardest by increasing cost-shares, and use of specialty drug coupons can encourage more adherence among affected members. A recent Prime Therapeutics LLC study cited a positive impact of drug coupons in making medications more affordable, ideally leading to greater adherence and better outcomes.

Medication adherence is an especially big challenge in the specialty space, with the following contributing factors:

- **Side effects.** Many new specialty medications have distressing side effects, some of which can be serious and require the patient to be monitored carefully and coached.
- **Complacency.** In the absence of side effects, patients can still have a difficult time remaining on their prescribed therapies, sometimes because they’ve become complacent.
- **Cost.** The high cost of many specialty therapies is a contributing factor. However, even in the Medicaid arena, where copays are either zero or a few dollars, non-adherence is an issue, meaning cost is not the only barrier to medication adherence.

**Cost-Sharing Statistics**

Flat copays in the non-specialty area can range from $10-$40. Within that range, MedImpact’s analysis – which used a combination of different market segments, including managed Medicaid – showed that members paid almost 21% of the drug cost. In managed Medicaid, copays are only a few dollars, at most; taking out managed Medicaid business brought the member percentage to about 25% for non-specialty drugs, which fits with the typical national average.

For specialty medications, copays have a broad range of cost. A flat copay could be as low as $25 or as high as $150. For coinsurance, the amount the member pays could reach several hundred dollars.

The analysis showed that for specialty, the average member paid only 2.58% of the total cost of the medication, a figure that suggests that PBMs and insurers are showing
restraint when establishing copay prices and setting them to reasonable levels. They have also instituted maximum out-of-pocket (OOP) limits, which help members. If the average cost for a specialty drug is $2,500, members who were charged the equivalent 25% of the cost (as in the non-specialty space) would pay a copay of $625.

In the past, prescription drug prices were determined by asking focus groups of potential patients what cost they would be willing to pay for a given therapy that relieves their symptoms and then analyzing those results and naming a price. Currently, pricing practices have little to do with the value of the product, although computer modeling of receptor sites in genotyping has improved this process for pharmaceutical companies.

**Cost Offset Models**

For a new agent coming to market, pharmaceutical companies are expected to show payers and stakeholders a pharmacoeconomic model at the time of the product’s launch. These “cost offset models” show the relative value of a new medication and determine the therapy’s cost for one year, as well as an analysis to determine the cost offsets. Cost offsets include the reduction or elimination of hospital stays, ER visits or physician visits. A pharmacoeconomic cost offset model shows the total annual cost of the therapy and the total cost offsets, demonstrating the medication’s net value.

Cost offset models are not common in the specialty pharmacy arena because there is often no evidence to show a cost offset that is higher than the cost of the medications. For specialty, cost analysis compares a new medication’s efficacy against the other medications already available on the market. If the evidence shows that the new agent is clearly more effective, then that medication will get a preferred tiering on the formulary.

Most of the time, however, the evidence is not sufficient to determine that a new drug is superior to existing therapies. In this case, payers need to look at the medications in the therapy classes and determine which one has the best price. When choosing the tier for the medication, designers will first take into account the drug’s effectiveness and then the cost. The most valuable medications will be those that have the highest effectiveness by evidence and the lowest cost.

**Samples vs. Coupons**

Historically, pharmaceutical companies would offer free samples, in which a physician would give a patient a supply of medication for several weeks to determine how well the drug would work before writing a prescription. In some cases, there was abuse in that system, and the drugs were often not very effective.

For specialty medications, because of the expense of the drugs, pharmaceutical companies did not want to waste these expensive therapies by giving them to physicians and hoping that they would be used appropriately. A new approach was the
concept of a copay assistance or coupon program, where there was a small risk to the person paying the copay to discover whether the new medication was going to be effective for them.

At this point, there is no clear consensus as to whether the coupon programs have a long-term benefit or harm in the specialty space.

Health plans and PBMs are using a variety of strategies to manage the use of specialty copay coupons, including:

- **Excluding specialty coupons.** For example, UnitedHealthcare Inc. publicized its decision to exclude coupons within their specialty pharmacy network. Plan sponsors can discuss the viability of this approach with their own health plan or PBM.

- **Drug exclusions.** Some PBMs have mandatory drug exclusions in their preferred drug lists in the specialty pharmacy space. For example, CVS Caremark Corp. excludes growth hormones, which fall under specialty pharmacy.

- **Preferred products and formularies.** This tactic is similar to drug exclusions. In it, the plan or PBM tiers different specialty brand products aligned with the preferred product and formulary placement to ensure that members are being driven to any existing lowest-cost alternative.

- **Step therapy.** For rheumatoid arthritis and multiple sclerosis – the two therapy classes with readily available generic alternatives – several PBMs and health plans have introduced step therapy programs. Members who want access to the non-preferred product have to step through the lower-cost therapies. Sometimes, this strategy drives higher rebate collection on behalf of PBMs and health plans for their plan sponsors.

- **Implementing a dispense-as-written (DAW) penalty.** This strategy makes members pay the difference in cost therapy if they select a higher-cost option.

- **Prior authorizations.** Health plans and PBMs can ensure that the member is receiving the appropriate medication for the appropriate diagnosis, particularly if the member is using the higher-cost or non-preferred brand medication within that specialty class.

Plan sponsors also have some strategies to consider, including:

- **Working with their health plans or PBMs.** For specialty therapeutic classes with lower-cost alternatives, sponsors can ask payers to help determine what solutions to offer members (preferred products or formularies, step therapy options or prior authorizations).

- **Leveraging the use of an inclusive or preferred pharmacy network.** Plan sponsors that want to basically exclude specialty drug couponing can adopt this method. In the current retail environment, there is no real way to hard-stop the claim or the coupon from processing, mostly because it processes as a secondary claim, and the retail pharmacy does not want to turn away its customers.

- **Member outreach and communication.** Once a plan sponsor has chosen a strategy, it should be sure to communicate that strategy to its members.
CellCept® Copay Card Program

One example of a copay assistance card is the “CellCept® Co-pay Card Program” (see box, p. 9). With this card:

♦ The member pays the first $20,
♦ The pharmaceutical company pays either up to $125 or up to $330 and
♦ The member pays any remaining balance.

Setting the Stage: Specialty Drugs

**Definition:**
- No industry standard; varies by source
- Drugs produced using recombinant DNA technology
- Drugs that require specialized expertise, handling and/or counseling

**Market:**
- 300 specialty drugs in market with 900 in pipeline
- 8 out of 10 drugs approved by FDA in next 5 years expected to be specialty
- Biosimilars not expected to produce same price drop as non-specialty generics

**Drug Spend:**
- Typically accounts for 12 - 30% of total drug spend, expected to be 40-50% (2020)
- Another 12 - 30% found in medical claims
- Average cost per patient is ~$2,000/month

**Utilization:**
- Typically 1 - 2% of population
- Utilization expected to increase 10% or more over the next few years, driven by new drugs; increased use as first line therapy; and new indications

**Trend:**
- 7 of 10 top drugs by revenue will be specialty in 2016 (5 in 2012)
- Expected to increase 15-17% (2012), 19-20% (2013), 22-25% (2014)
For patients demonstrating financial need, the CellCept® copay card pays up to $330 a month, under the following circumstances:

- The patient’s household adjusted gross income is less than $100,000 per year.
- Patients need to provide a verbal statement to verify their income when they enroll, although documentation at a later date may be required.

An analysis of this copay coupon program was based on a 30-day supply or 90 tablets of CellCept, which is a transplant drug. (See box, p. 9.)
In this case, the copay was $150 to the plan, but because of the copay card, the member paid $20, the pharmaceutical company paid $130, and the payer ended up paying $1,043.72.

There is no copay assistance program on generics, but if the patient had used the generic mycophenolate, there is a substantial difference to the payer. (See box, below.)

<table>
<thead>
<tr>
<th>Adult dosage</th>
<th>1.5 gm per day (three 500 mg tabs per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AWP price per 500 mg tablet</td>
<td>$15.79</td>
</tr>
<tr>
<td>AWP monthly price for 90 tablets</td>
<td>$1,421.10</td>
</tr>
<tr>
<td>Typical discounted price per month</td>
<td>$1,193.72</td>
</tr>
<tr>
<td>Copay for the plan</td>
<td>$150.00</td>
</tr>
<tr>
<td>Copay assistance per month of therapy</td>
<td>$130.00</td>
</tr>
<tr>
<td>Patient pays</td>
<td>$20.00</td>
</tr>
<tr>
<td><strong>Plan pays</strong></td>
<td><strong>$1,043.72</strong></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Adult dosage</th>
<th>90 tablets per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAC pricing per tablet</td>
<td>$0.89</td>
</tr>
<tr>
<td>Cost per month of therapy</td>
<td>$86.40</td>
</tr>
<tr>
<td>Copay for the patient</td>
<td>$10.00</td>
</tr>
<tr>
<td>Difference to the patient</td>
<td>$10.00</td>
</tr>
<tr>
<td><strong>Difference to the payor</strong></td>
<td><strong>$967.32</strong></td>
</tr>
</tbody>
</table>

Taking a maximum allowable cost (MAC) of $0.89, the cost of therapy for one month would be $86.40. The patient would pay $10, and the payer would pay $76.40.
The difference between the brand-name CellCept® and the generic to the member would be $10; the member actually would pay less, and the difference to the payer was $967.32. Mycophenolate is an AB-rated generic medication — meaning that it meets bioequivalence requirements — and according to the FDA, there is no difference between the brand and the generic product except for the cost.

While some payers would require the generic drug to be used, this is not foolproof because in many states, the physician can override the generic requirement by writing “dispense as written” or similar language on the prescription.

Instructions to patients when they receive a copay assistance program typically say that, to help ensure receipt of the brand-name drug, the patient should ask the doctor to specify the brand with a note that states:

◆ **No substitution,**
◆ **Brand-name medically necessary or**
◆ **Dispense as written.**

The terminology is dependent on the state in which the patient lives. In these situations, pharmaceutical companies are telling their members to insist on a brand-name product because it is medically necessary, which is not the case.

Patients hear about these programs by receiving a card or a post card when they obtain the medication from their doctor, but in many cases, these programs are used by the specialty pharmacy.

Specialty pharmacies communicate their copay assistance programs by filling the prescription and explaining to the patient what the copay is. If the patient expresses any concern about the cost (or even if he or she does not), the specialty pharmacist can help the patient take advantage of one of these programs.

Specialty pharmacies are motivated to communicate with members about these programs and expedite the copay assistance because they don’t want to delay getting patients on to their medications. The payer shares this goal, but also is motivated to ensure that the most valuable medication is being prescribed and taken.
Case Study: UnitedHealthcare

United Healthcare is one example of a company that has taken steps to address the use of copay coupons for specialty medications. The company started its program in September 2012, when it had a three-tier benefit program. At the time:

◆ 75% of its members using a tier-three (non-preferred) drug were also using a copay assistance card program and
◆ 45% of the time, when a patient was using a medication on tier three, a lower-cost alternative was available.

This situation costs the health care system more money, so for United, the copay assistance programs were providing a way around the formulary tiering, which is intended to financially incentivize patients to take the most appropriate medication and aim for the highest value.

United worked with its own specialty pharmacy and others in its network to stop allowing the copay assistance programs in four therapy classes:

◆ Multiple sclerosis, where United disallowed the programs for Extavia® and Gilenya®;
◆ Autoimmune, where United would not allow the copay programs for Humira®;
◆ Transplant drugs, where United disallowed the programs for CellCept®; and
◆ Hepatitis C, where the company would not allow the copay assistance program for Victrelis® and PegIntron®.

For each therapy class, other medications were available that, from United’s perspective, had higher value.

United developed a high-touch program to reach out to members and explain the new approach. The insurer also asked members if they would like a customer representative to contact their physician to discuss switching medications.

For Humira® and CellCept®, the new program meant an outreach effort to over 3,000 members. Upon receiving an explanation of the program and the invitation to contact the physician, 21% of the members said they would like that kind of assistance. Of the 79% who refused the service, only 3% indicated it was because they had already tried a lower-cost alternative. The majority indicated that “cost was not a concern.”

One-third of United members who asked for the specialty pharmacy to reach out to the prescriber saw that the medication was actually changed; 23% of members reached out to the prescriber on their own and were switched to the lower-cost drug.

When instituting a switch program, insurers need to keep an eye on how many people stop taking their medication. In the case of United’s TNF inhibitor class, 20% of the patients stopped taking therapy. While this could be considered a result of the switch, United did a similar analysis of a controlled group who was not affected by
this program and found that 22% of those people stopped taking their medication in the same time period.

Because of that analysis, United concluded that the non-compliance didn’t result from the cost or the switching. The insurer did further analysis to see what impact total copay cost had on switching and found that members with more nominal copays ($50-$60) only switched about 10% of the time, while for those with much higher copays (such as a 25% coinsurance), the switch was made 40% of the time.

The final results of United’s program showed a five-point decrease in tier-three utilization and a market shift of 10% within the TNF inhibitor category. Because of the program’s success, the insurer has added 25 additional specialty medications to its list prohibiting the use of copay assistance cards.

**Montana Association of Healthcare Purchasing’s Experience**

The Montana Association of Healthcare Purchasing (MAHCP) is an organization with multiple employers, both in and around the state of Montana, and is one of MedImpact Healthcare System’s clients. MAHCP uses a sophisticated seven-tier formulary benefit that exceeds what is normally seen in a commercial population. This benefit includes three tiers in specialty, and there are significant copays on the highest tiers of specialty benefit. MedImpact has worked with MAHCP to help the organization understand the influence of copay assistance programs on its formulary design.

For MAHCP’s client, the 2013 specialty spend was just over $9.7 million, and the copay expected was $678,212. The actual member contribution, after the copay assistance programs, was only $30,391, reducing the copays by 96%. Through this structure, members utilize much higher copays for medications that are extremely expensive, but show low clinical differentiation. Copay assistance programs counteract their benefit designs and thwart motivation to comply with the evidence-based formulary. MedImpact is working with MAHCP to develop a program similar to United’s that will help curb the influence of those programs when they are financially disadvantageous.

In some cases, copay assistance programs are being used to lower health care expenses. For example, hepatitis C medication Sovaldi’s manufacturer Gilead Sciences, Inc. uses a program for the drug in which the member pays $5 for the prescription, while Gilead pays up to 20% of the drug’s cost. MedImpact set up a benefit for a client where there was a 20% coinsurance with no member maximum. With the benefit, the client received a 20% discount on Sovaldi, and its members pay $5.

**Looking Ahead**

Expert projections suggest that within five years, specialty medications will represent about 50% of drug spend, meaning the cost of the medications will rise, but the percent of the member contribution will decrease. The 4-6% spend contribution by the
member will represent 50% of the drug spend, presenting a double-edged sword for the payer.

Payers can combat this by establishing strict utilization management criteria and step therapy and by blocking non-valuable medications wherever possible. Beyond that, payers should also collect accurate data to determine where it makes sense to disallow copay assistance programs and selectively choose therapy classes and clients. Payers should also include a member education program in this effort to make it easier on the member as these switches occur.
Q&A Session

Question: Could you just quickly explain what you were referring to when you mentioned the max price for the generic CellCept®?

Avey: Maximum allowable cost: We have sometimes some substantial copays on specialty medications. But typically, especially what you’ll see in coinsurance, is it may say 20% of the cost of the drug, but there is a max out-of-pocket, let’s say of $300, so you’re not going to see a $625 copay. It will protect the patient that way. And then the other way you see it is that can be an annual max out-of-pocket. So, even if somebody had, for example, a $600 copay, the max out-of-pocket may be $2,000. After they’ve gotten their prescriptions filled three times they would hit that max, and then the rest of the year they would pay no copay at all.

Question: You mentioned that 75% of United Healthcare members were using a tier-three drug with a coupon associated. And given that the copay card is adjudicated by a secondary party, how was United able to track the coupon usage, and is that kind of tracking present in other institutions as well?

Avey: The fact of the matter is that United Healthcare owns their own specialty pharmacy, and so they can get the information directly from them. We contract with multiple specialty pharmacies, and we actually can collect that data from them. That data, by the way, is reported back to the pharmaceutical companies routinely so that they know how often those programs are being used, and obviously there is a financial charge to them as well.

Question: You gave an example of the Montana Healthcare CO-OP, and I was curious on how much of this copay card restriction and exclusions list, how much of that is driven by employers and how much of that is driven by say, MedImpact personally, and what has been the response from your customer base in general?

Avey: With that program, that analysis I just gave you was done just two weeks ago, so nothing has been done to counteract the programs yet. We just did that analysis and so now we’re developing a program that will help deter what impact those programs are having. So, there’s been no action to date yet with that program.

And I will say one other thing about MAHCP because I mentioned that it’s really important for you to analyze by client and by therapy class. They had come to us about a year ago and felt like they were having some problems in the oncology space and they asked us to do an analysis there. We did the analysis and we found out actually that in that case the impact of the cards was not significant enough to warrant having a program to limit the use of the copay cards. They elected not to do anything. We told them we would do anything they wanted but when you looked at the numbers, it didn’t make sense. And that’s why I was making a really strong statement that you have to do these programs based on analysis that you’ve done to determine exactly what the pain is.
Question: And also the analysis that you did, did that just indicate that within the oncology space there was a lot greater adherence advantages that came from the copay card usage?

Avey: No, actually it was because the number of prescriptions that were being filled was not significant enough to warrant the administrative cost of the program.

Question: How do you see expansion of these exclusion and restrictions lists going beyond just rheumatoid arthritis and multiple sclerosis?

Avey: I think as in the case of United Healthcare, they broadened it as they indicated to 25 medications. There are clearly places in almost every therapeutic category. I wouldn’t even want to limit it. But we know for sure that what you do by the way when you do that kind of analysis, is you rank your therapeutic categories and of course autoimmune always comes out number one with almost everybody. Multiple sclerosis, oncology, growth hormone — those are all typically in the top five.

And so what you want to do is start with where are your highest cost therapy classes and then look at them by drug and find out how many non-preferred medications we’re using. And where you have high costs in an area and you have a lot of non-preferred medications being used, that’s where you would typically want to do an analysis and say, “You know, would doing a program be exempt in this therapy class?”

Question: Looping back to the very beginning you caught my ear on the topic of biosimilars. Is there actually any biosimilar on the market in the U.S. today, and what is it? And if not, what is likely to be the first biosimilar that comes on the market?

Sandhu: To my knowledge there currently are no biosimilars. And as far as the pipeline goes, I don’t know if there are any fundamental ones. I don’t think there are right now. I think it’s still kind of facing challenges to reach the U.S. market.

Avey: I would add to that: The only one that has been kind of identified is Enoxaparin, which is the biosimilar of Lovenox, that’s been on the market for a couple of years. That’s really the first one that entered the United States; there are no other ones that I’m aware of on the market.

And of course, the problem in the U.S. is that the Food and Drug Administration only recently put out their new guidelines in terms of how they’re going to review and analyze biosimilars in the United States. We keep looking for these to be available — there are a lot of pharmaceutical companies that are dumping a lot of money into development of them. But it kind of looks to us like we’re probably two years away before we really see any movement in that arena.

And, as Alaina pointed out, this is going to be a very interesting place in the market and it’s going to depend on the actual price of the biosimilar. If the biosimilar only gets a 20% discount, as Alaina alluded to, and those are the numbers we’re hearing on the street. If it’s only 20%, then of course the brand-name innovator company could come back and just offer a 20% rebate on their product, which would severely limit how much biosimilar use there would be.
You’re probably aware that there’s a generic Copaxone® that is supposed to hit the market any day, and there are some court battles being fought there. But we understand Mylan will come to market with a generic Copaxone® that is kind of what we would see if this kind of a product came out on the market. And so we’ll see if indeed Mylan launches and we see what kind of discount they have on that product. It might give us some indication at where a biosimilar would need to be priced in order to see a significant uptake.

**Question:** On the program that UnitedHealthcare put in place — I think you said in the fall of 2012, so it’s been around at least 18 months — have Aetna and Cigna also instituted similar programs, and if not, why not?

**Sandhu:** I don’t believe they have.

**Avey:** Both of those companies are usually very forthcoming when they have programs in place like that. They’ll tout them and say “this is really working exceptionally well for us.” And so the question that you ask is a really good one: So why haven’t others? Actually, CVS Caremark has done some work in this arena, and as I’ve pointed out we’re starting to do some work in this arena.

I think basically it comes down to the point I made about the landscape changing so rapidly. And things that people wouldn’t think about doing two years ago are now saying, “I’m willing to do that,” and I’ve clearly heard that in the copay assistance arena.

I know specific clients that two years ago said, “I just don’t want to address any member disruption that might occur,” and today they’re saying “Let’s look at this program and see if we need to do something about it.”

**Question:** Do you have a sense of how many specialty drugs or categories associated with coupons have lower-cost alternatives?

**Sandhu:** Off the top of my head, I don’t. I think with specialty within rheumatoid arthritis and multiple sclerosis, they tend to be the top or higher therapeutic costs when it comes to specialty in general, and those do have lower-cost alternatives. But I think for the other therapeutic classes in specialty, which may have a lower utilization, that the availability of those is much lower. But I don’t know that statistic offhand.

**Avey:** I have a little bit of a sense for it, and I agree with what you just said. Basically what we see is where there are multiple drugs within a therapeutic category there’s more likely to be copay assistance programs. That is why you see them in multiple sclerosis and autoimmune so much.

We see that in categories of where there are maybe one or two alternatives, we don’t see those programs near as much. I think it’s why the pharmaceutical companies are trying to get their medications utilized, and they’re obviously trying to counteract the formulary tiering that we’re using where we prefer a different agent then what they have. If there’s no real risk of losing market share to another agent, then you’re not really seeing a lot of those.
Question: In the compass of your discussion, it seemed that there were different tiers of a specialty medication. But many times in plans today there is a single tier for a specialty medication, and sometimes in some categories, all of the medications are in that specialty tier. What do you do then about copay programs in that case?

Avey: That’s a really good point, and you’re absolutely right. We see a lot of plans that will have three tiers for non-specialty and then a fourth tier for specialty. And it’s only one tier, but that goes back to the point Alaina made, where through step therapy and through your prior authorization criteria you set up programs where a preferred agent must be used first before we will even allow a non-preferred agent to be utilized. That’s the way that you best counteract the copay assistance programs because you can’t use it because we’re not going to allow you to use the medication.

Question: On Sovaldi — you are right where the carriers are hearing so much about this drug costing anywhere from $84,000 to $154,000 for treatment. I just want to know what your reasons are to agreeing that this is a good copay assistance program because this drug is more effective than others in its class.

Avey: The reason that that makes sense to us is because from the assessment that we did at the time Sovaldi came out on the market, from the evidence that we reviewed, we saw that Sovaldi was more efficacious than either Incivek or Victrelis, so that was put on our preferred tier. Now to us, the way that you manage hepatitis C is not by promoting a protease inhibitor that may be less effective but to make sure that it’s appropriate for a patient to receive any therapy at all.

And there’s a lot of push that any person that has been shown to be infected with HCV should be treated, and we don’t believe that that’s the case. And if you talk with hepatitis experts across the country, they all indicate that 20% of patients will develop kind of a natural immunity to hepatitis C, and they know they will never to go to chronic disease and will never see any kind of liver damage.

We don’t want to treat people that it’s inappropriate to treat unless we know that in fact they’re seeing damage to their livers. We look at hepatitis C as being treated by or being managed more effectively by that, screening patients to make sure that it’s appropriate. But what we believe is that once you’ve found somebody that is appropriate for therapy then we want to use the best drug. And are we happy about the cost? No, we’re not happy about it at all, but to be honest with you, if the client, the payer is paid a 20% lower amount, as in this program that I described, that’s lower than the cost of Incivek and Victrelis, which as you know may require much longer therapy with Interferon and Ribavirin. So to us, that’s kind of a win all the way around.

Question: How do the copay assistance programs work with members with high-deductible health plans? Is there still some process of meeting those large deductibles?

Avey: You bring up a really good point that we’re in the process of reviewing right now, which is if a member is actually receiving that benefit, then we’re in the process of reviewing, and obviously CMS is reviewing this at this time as well, talking about charitable contributions that are made. (See Appendix E for CMS’s guidance on this
issue.) We’ve been talking about the programs that pharmaceutical companies come out with. But there are also charitable foundations that also will provide funding for members who have a hard time paying for their specialty medication.

But the point of the matter is that today since we don’t have across the board information for what copay assistance programs are being utilized, the max out-of-pocket or deductibles, the copay assistance programs are not being taken into consideration.

**Question:** Both of you talked a little bit about the importance of monitoring or tracking the coupon use and how difficult it is. So is your best recommendation for that is to just work with the specialty pharmacies? And Steve, you motioned that MedImpact would be working or at least is talking to specialty network pharmacies about limiting the use of some coupons. So I am curious about what the feedback has been from the specialty pharmacies.

**Avey:** The ones that we have under contract have been willing to both provide us with information and are willing to discuss those programs that we could put in place that would limit them. But again, it goes back to being a good partner, and I want to look at it and make sure, because administratively it is a lot of work on their part, to shut off the use of those copay assistance programs for a specific client that requires a burden on their part to figure out administratively how you do that. So we try and work with them, get the information and you know our commitment back to them is that we’re not going to ask them to do it for everybody, in every situation. We’re going to do it where it makes the most financial sense.

**Question:** How is the role of contracting changed for payers and PBMs after the implementation of restricted and exclusion lists?

**Sandhu:** It puts you in a stronger position for rebate negotiations, for tighter formulary restrictions, etc. So I would say it’s probably kind of like alongside with preferred step therapy programs you typically see enhanced rebates. I think it would give the payer more negotiating strength.

**Question:** How long do these specialty copay offset programs last? Are they for one year typically?

**Sandhu:** The ones that I’ve seen are about six months.

**Avey:** I think it’s across the board, and it depends on the therapy class; there are a lot of things that it depends on. I have seen some that are year-long, but I don’t think there’s a cut rule that’s on them.

**Question:** Is it legal to make a rule and plan design that allows for higher copay for specialty until the deductible is met and then change it to a lower copay?

**Avey:** Except for the government programs, which have specific regulations for the way things are done. But in the commercial space, yes it’s legal to do that; you can have benefit designs that do that.

**Question:** Have you heard any feedback, positive or negative, from Gilead regarding the plan sponsor who adjusted their copay design?, Also, was the 20% coinsurance for Sovaldi?
Avey: I am laughing because I am telling you that one is brand new — I did not know that program existed until yesterday. So no, I have not had any conversations with Gilead, but it will be interesting to see what Gilead’s response is to that. That was my first thought when I heard that that program had been put in place. I like it because the payer gets a 20% discount, I think it’s great. I don’t know what they’re going to say about it.

Question: The 20% was only for Sovaldi, not other specialty drugs?

Avey: It was just Sovaldi.

Question: Are you seeing pharmaceutical manufacturers offering rebates for competing specialty medications to incentivize PBMs to lower the tier of the specialty drug with a rebate? If so, how often are you seeing pharmaceutical companies offering these rebates?

Avey: Yes, we are seeing those. And again it goes back to kind of the therapy class, how many competing products there are within that class, but yeah, we’re seeing those routinely.

Question: And how do these drug coupons work with health savings accounts? The member is responsible for the first dollar spent.

Avey: Again, I’m just having this conversation. We’re going to have to go back and better understand all of these issues with the payment upfront, the deductible upfront. Because the way the adjudication system operates, we don’t really see the copay assistance cards, and that’s why we rely on our specialty pharmacies to give us that data, because what comes back to us, it appears that the copay was paid. And so in a health savings account or anywhere with a plan with a deductible, it appears the member paid that much money. That opens up a whole area of interest in terms of when those copay programs are being utilized.

Sandhu: I would agree, too, with the high deductibles and the health savings accounts because it’s processed as a secondary claim. I would completely agree — I think I’d want to have greater detail on how that would come back to the member.

Question: Do either of you know whether United allowed a patient assistance program to satisfy the patient’s deductible on a high deductible plan?

Question: Steve mentioned that programs need to be tailored for patients and for therapy. How do you see therapies indicated in multiple indications being managed, especially for blanket copay card restrictions? An example would be Rituxan for RA and oncology.

Avey: Yes, that’s of course we know what it’s being used for by the prior authorization criteria so we can tell what the drug is actually being used for. So that’s a communication. As you probably know, the specialty pharmacy knows all that information because they not only help with the copay assistance programs. They also work with the physicians’ offices to get the data that is necessary for the prior authorization criteria. So we would be able to tell from the prior authorization what the medication is being used for.
Appendix A: AIS Coverage of Copay Coupons

United Copay Coupon Program Shows Some Success; Plan Will Add 25 Drugs

On Jan. 1, 2013, UnitedHealthcare implemented a novel initiative that would limit the use of manufacturer-sponsored copayment coupons though its specialty pharmacy network. The launch was preceded by a high-touch member outreach and support campaign to help ensure the program’s success. This program took a more aggressive strategy than others the plan had taken to manage specialty therapies — and it seems to have been an effective one, as United recently said that it would be adding another 25 specialty medications to the initiative as of Jan. 1, 2014.

Although some payers have been limiting coupon use among their members, most of the activity so far has been in the nonspecialty space. But it’s not for a lack of potential targets: According to Zitter Health Insights, among 114 biologic brand drugs, 78% of them had copay offset programs.

In September 2012, when United’s program was first unveiled, the company said that 75% of its members taking a Tier 3 drug were using a coupon. In addition, 45% of its members were taking a Tier 3 drug even when one on a lower tier was available. Rather than dumping all of its specialty drugs in the highest tier, the plan places those drugs on different tiers “based on the specific health care value each one delivers.”

Before this program, said Lida Etemad, Pharm.D., vice president of pharmacy management for UnitedHealthcare Pharmacy, the plan had used such strategies as step therapy and product exclusion to manage specialty drugs. But with the newer program, United took the step of having its network specialty pharmacies not accept coupons for certain specialty medications at the point of sale.

There were six drugs in the program’s initial launch: multiple sclerosis drugs Extavia (interferon beta-1b) and Gilenya (fingolimod); transplant drug CellCept (mycophenolate mofetil); Humira (adalimumab), which is approved to treat rheumatoid arthritis, Crohn’s disease and psoriasis; and the hepatitis C drugs Victrelis (boceprevir) and Peg-Intron (peginterferon alfa-2b). Each of the therapeutic categories affected had Tier 2 specialty drugs available. Members’ out-of-pocket costs for the lower-tier drugs would be similar to their costs for the Tier 3 drug using a coupon, said United.

When United rolled out the program, “we knew we needed a high-touch member support campaign,” said Etemad at the Magellan Pharmacy Solutions 10th Annual Oncology Summit held Sept. 19, 2013, in Baltimore. The plan sent out letters 45 days before the program was implemented, and if members called to refill one of the included drugs, they were rerouted to a call center, where staffers explained the program.
United also gave members the opportunity to have specialty pharmacies reach out to physician offices. “The goal was to hand-hold members all the way through the process,” she explained, adding that all of the member interactions were logged into an internal tracking tool. “We had a very tight roll-out plan…and a very intense preparation and follow-through to implement the program.”

An early program analysis revealed the following:

- **The largest member base was for people taking Humira and CellCept.**
- “Just under 3,000 members had contact with the specialty pharmacies,” said Etemad.
- **During contact with the specialty pharmacies, 21% of those members** “indicated they would like the specialty pharmacies to do outreach to the physician’s office, while 79% declined outreach.”
- **Of those turning down the outreach offer,** 3% said it was because they had “prior use of a lower-cost alternative,” but the majority said it was because “cost was not a concern.”
- **One-third of members who authorized outreach and 23% who spoke with their physician on their own switched to a lower-cost alternative.**
- **Overall, said Etemad, “43% of members had an interest in a lower-cost alternative.”**

### The Prevalence of Co-Pay Offset Programs

**Key Findings**

Seventy-eight percent of biologics have a co-pay program, the majority of which are focused on chronic diseases.
In the tumor necrosis factor (TNF) inhibitor category, 180 days of baseline data from members taking Humira who had pharmacy and medical benefit eligibility were compared with follow-up data through March 15, 2013. That information showed that there "were a few more women than men who switched to a lower-cost alternative," Etemad said. In addition, for those members who were at least 41 years old, "the switch rate was much higher" — almost 16%, compared with an overall switch rate of 13.9%. Members in the Northeast had the lowest switch rate, less than 6%, while those in the Midwest had the highest rate, at 16%.

"The switch rate was lower for Humira users with Crohn’s" — 5% — she explained, and it was only 2% for those with "no evidence of TNF-related diagnosis." In addition, "the switch rate was similar for [Humira users] with psoriasis, psoriatic arthritis and rheumatoid arthritis and users with multiple conditions."

Another observation was that the baseline data were a "good predictor of overall health status," as members on Humira who visited the emergency room or were admitted for an inpatient stay were less likely to switch than those who had not experienced either of these events.

Perhaps not surprisingly, "as members’ total pharmacy costs went up, so did the switch rate," explained Etemad. If members were taking "five or more medications, they were more likely to switch." Likewise, "the cost share that the member would now face" also had a big impact. For those with a copay of $50 to $60, the switch rate was "just over 10%," but for those with 25% coinsurance, the switch rate was more than 40%.

"Interestingly, the deductible didn’t matter," said Etemad, although she added that it was unclear why.

The plan saw a "five point absolute decrease in Tier 3 utilization" and a market shift of more than 10% within the TNF inhibitor category, said Etemad. "From our perspective, this was extremely successful. It’s something that’s starting to give us some impact on this marketplace."

However, she noted, "We were very concerned about the program’s impact on discontinuation” of drugs to treat the different conditions. She explained that “20% of Humira users did not fill a prescription for Humira” or an alternative therapy through March 15, 2013. “We wanted to benchmark this — was it due to the coupon program?” So United looked at members who filled other TNF inhibitors who were not included in the program, as well as some historical controls. Those data showed a similar no-fill rate — 22% — for this group.

Etemad acknowledged that the 20% no-fill rate is “not a good thing, but it made us feel comfortable” that the copay coupon program wasn’t driving it up.

In the transplant category, with CellCept, which Etemad noted has an AB-rated generic — meaning that it meets bioequivalence requirements — United saw a 34%
market shift. With Gilenya, though, “we had no impact on market share in the class,” and the plan is performing an analysis to try to determine why, she said.

But overall, said Etemad, “a significant impact was measured as a result of limiting the facilitation of coupons.” Because of that, United will add 25 specialty drugs to the program on Jan. 1, 2014. Therapeutic categories include growth hormone, which will see Genotropin (somatropin [rDNA origin]) added to the list, as well as hepatitis B, hepatitis C, infertility and others.

**Insurers, PBMs Take Varied Approaches to Addressing Specialty Drug Copay Coupons**

Many health plans and PBMs agree that copay coupons offered by makers of traditional brand-name drugs thwart formulary compliance, and have attempted to combat their use through tactics such as enlarging copay differentials and applying utilization management. But when it comes to coupons and discount programs associated with high-cost specialty drugs, payers are taking a more selective approach, as these programs may improve medication compliance by offsetting a patient’s financial responsibility. UnitedHealth Group’s UnitedHealthcare unit, for one, has launched a widely publicized initiative limiting the coupons, while PBMs like Prime Therapeutics LLC and MedImpact Healthcare Systems, Inc. subsidiary ScriptSave suggest there are ways to embrace them.

Whereas the issue around traditional coupons is “rather simple,” addressing specialty drug coupons is “very nuanced,” observes Pat Gleason, director of health outcomes at Prime Therapeutics LLC. “With the small molecule drugs…we feel that coupons simply circumvent the formulary, leading to the use of more branded products when there are equally effective, safe generics that are very inexpensive, and just add cost to the system,” he told AIS in October 2013.

But the specialty realm presents medication compliance and therapy abandonment concerns that are closely tied to cost share, which is often higher for specialty drugs, even preferred agents, he says. “I understand the philosophy of ‘there’s more skin in the game’ [with higher cost share]. But then you’ve got the corollary issue of, as you get above $150 a month, people may choose to abandon therapy and that’s not what we want,” says Gleason. “We want to help people get the medicine they need to feel better and live well.”

As a result, Prime currently allows the use of coupons and patient assistance programs (PAPs) for both preferred and nonpreferred specialty agents, and recently quantified members’ cost savings associated with those discount programs with new research presented at the Academy of Managed Care Pharmacy’s (AMCP) Nexus 2013 conference held Oct. 15-18, 2013, in San Antonio.
To determine the impact of discount programs, Prime looked at prescriptions filled between January and June 2013 for 17 different specialty drug categories by its own Prime Therapeutics Specialty Pharmacy. That entity created a file for each prescription that contained detailed information on the pharmaceutical manufacturer coupon or PAP amount reimbursed to offset share. The file was then linked back to the PBM claim records to identify pharmacy only claims that were final paid claims.

Of the nearly $418 million spent on drugs during the study period, Prime determined that members were responsible for 5.2% — or close to $22 million — of total costs. Coupons and/or PAPs were associated with 47,924 (38.2%) of 125,303 prescriptions and totaled more than $10.6 million (48.6%) of the member share offset. In other words, coupons and PAPs were applied to four out of 10 prescriptions going through the Prime Therapeutics Specialty Pharmacy.

Moreover, the cost share for 40% of claims prior to the use of coupons/PAPs was $50 or less, whereas with the coupons, individuals’ cost share dropped below $50 fully 95.6% of the time. “That’s a pretty dramatic shift,” says Gleason. The autoimmune category had the most specialty pharmacy prescriptions and accounted for $153.6 million total paid; the members’ share was $10.5 million (6.8%), of which nearly $8 million (73.4%) was offset by coupons/PAPs.

Gleason adds that while the study included PAPs, about 90% of the discounts applied were from coupons. The difference between the two, he explains, is that coupons are directly administered by the pharmaceutical manufacturer, while PAPs are usually administered by a nonprofit third party, sometimes sponsored by a manufacturer but not always, and typically require that the patient have an income below a certain level.

**Prime Optimizes Use of Specialty Coupons**

In conducting the study, the PBM was “just trying to get an understanding of what’s happening with specialty coupons in order to build better benefit designs,” explains Gleason. As of now, the PBM is “optimizing” all coupons, applying them to both preferred and nonpreferred formulary agents. “We’re reaching out to the members to encourage them to use the preferred specialty products, but we’re not blocking coupons for the nonpreferred specialty products,” Gleason tells AIS.

Also presenting at the AMCP conference was UnitedHealth Group’s UnitedHealthcare unit, which in 2013 began disallowing coupons for six drugs going through its network specialty pharmacies. Effective Jan. 1, 2013, the insurer’s network specialty pharmacies stopped accepting coupon cards when a member calls to fill a prescription for one of six drugs: Extavia (interferon beta-1b) and Gilenya (fingolimod) for multiple sclerosis, CellCept (mycophenolate mofetil) for patients receiving transplants, Humira (adalimumab) for rheumatoid arthritis, and Victrelis (boceprevir) and Peg-Intron (peginterferon alfa-2b) for hepatitis C. The action does not impact needs-based assistance programs.
Speaking at AMCP and at the Magellan Pharmacy Solutions 10th Annual Oncology Summit held Sept. 19, 2013, in Baltimore, Vice President of Pharmacy Management Strategies Lida Etemad, Pharm.D., said the key to a successful implementation was a “high-touch member support campaign” that included letters sent to members 45 days before the new program took effect. If members called the specialty pharmacy to refill one of the included drugs, they were rerouted to a call center, where staffers explained the program. United also gave members the opportunity to have specialty pharmacies reach out to physician offices.

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◆ Overall, said Etemad, “43% of members had an interest in a lower-cost alternative.”

Perhaps not surprisingly, “as members’ total pharmacy costs went up, so did the switch rate,” explained Etemad. If members were taking “five or more medications, they were more likely to switch.” Likewise, “the cost share that the member would now face” also had a big impact. For those with a copay of $50 to $60, the switch rate was “just over 10%,” but for those with 25% coinsurance, the switch rate was more than 40%.

United will add 25 specialty drugs to the program on Jan. 1, 2014, according to Etemad. Therapeutic categories include growth hormone, which will see Genotropin (somatropin [rDNA origin]) added to the list, as well as hepatitis B, hepatitis C, infertility and others.

“Regarding other products, we do allow for the adjudication of coupons for products that are lower cost alternatives to the products included in the program,” Etemad clarifies in an email to AIS.

While the Prime study concluded that specialty pharmacies should consider optimizing the use of coupons and PAPs in an effort to improve drug adherence, that doesn’t mean Prime won’t consider blocking the use of certain specialty drug coupons in the future. “I think [the United effort] is very interesting. We learned from that program and may very well be doing something similar in the near future,” says Gleason. “But at this point in time, we’re optimizing all coupons.”
Plans, Pharma Could Align to Offer Cards

Meanwhile, another PBM executive suggests that health plans take a targeted approach when it comes to allowing or disallowing the use of coupons. “I think the knee-jerk response and managed care plans’ frustration is, ‘Oh, you’re screwing up my formulary.’ But I think those cards can be used in a more directed and strategic fashion than today’s shotgun scatter approach,” says Marcus Sredzinski, Pharm.D., executive vice president of pharmacy with the “consumer-focused” PBM ScriptSave, now a wholly owned subsidiary of MedImpact Healthcare Systems, Inc.

Sredzinski says he believes there are yet unexplored ways for pharmaceutical manufacturers and plans to work together to “reward” members with discount cards. For example, for specialty conditions like hepatitis C or multiple sclerosis, a plan could “work with the pharmaceutical company [offering] the copay card — maybe even [on] a preferred product in the class — get a patient on board with the product, waive the first copay with the copay card and then track the patient through time,” Sredzinski tells AIS. “So to incent compliance we’ll say, ‘We’ll reduce the cost of the drug at the point of sale through a copay card, so if you pick up the drug on time or you hit a certain biomarker, you get rewarded through a copay waiver or a buy-down in your copay.’” Sredzinski adds that something similar could be done with diabetes patients who show improved A1C levels over time.

“I don’t think the marketplace has looked at copay cards in that fashion and it’s something I would like to do,” he says. “Could it upset the formulary balance? Sure, but why not align yourself with [the cards] and work in a different fashion? I think the pharmaceutical companies obviously have the money; in their copay cards they’ve underwritten net value in their marketing budget.”

HHS Communications on Copay Cards Lead to More Confusion Than Clarity

As qualified health plan (QHP) sponsors prepared for the Jan. 1, 2014, implementation of federally facilitated and state-based exchanges, they received long-awaited clarification in October 2013 that the use of copay cards will be allowed in the new marketplace (see Appendix D). But several industry observers say opponents of the discount programs shouldn’t throw up their hands just yet, thanks to a second communication from HHS that only muddied the waters. As a result, they advise drug companies sponsoring the cards to proceed with caution.

“Right now the status of copay coupons or cards is pretty up in the air with respect to exchanges,” observed Caroline Pearson, vice president at consulting firm Avalere Health LLC, in fall 2013. “At this point, I think we have no idea where we’re going to land.”
In an Oct. 30, 2013, letter to Rep. Jim McDermott (D-Wash.), HHS Sec. Kathleen Sebelius indicated that QHPs and other programs related to public exchanges are not considered federal health care programs and would therefore not be subject to fraud and abuse laws, including the federal Anti-Kickback Statute. Since individuals buying insurance through the exchanges are eligible to receive premium tax credits and cost-sharing subsidies, the ranking member of the House Ways and Means Subcommittee on Health had asked Sebelius for clarification on the status of QHPs and other programs participating in the exchanges.

**Coupons in Exchanges Are Murky**

Several days after the HHS letter, however, an answer to a frequently asked question (FAQ) posted on Nov. 4, 2013, to the CMS Center for Consumer Information and Insurance Oversight (CCIIO) website said HHS has “significant concerns” with the suggested practice of third-party providers and other companies supporting premium payments and cost sharing in the plans, “because it could skew the insurance risk pool and create an unlevel field in the Marketplaces.” Moreover, the FAQ stated, “HHS discourages this practice and encourages issuers to reject such third party payments.”

The Pharmaceutical Care Management Association (PCMA) immediately pointed out that the FAQ appears to be a deviation from Sebelius’ letter. The PBM trade group has repeatedly lobbied against the use of copay cards in the exchanges, and argued in a Nov. 5, 2013, statement responding to the FAQ that these “and other kickback schemes are designed to induce patients to ignore formularies, networks, and other tools that make benefits more affordable by encouraging patients to choose generic drugs and other less expensive options.” Copay coupons are not allowed in Medicare, Medicaid and the Veterans Affairs pharmacy program because they are considered kickbacks under the statute. “Now regulators need to take the next step and formally determine what everyone already knows: that federal anti-kickback laws apply to the [Affordable Care Act],” added PCMA President and CEO Mark Merritt in the Nov. 5, 2013, statement.

While the FAQ can certainly extend to copay cards, Pearson says she believes the greater concern to HHS and to plans is the idea of hospitals attempting to convert “frequent fliers” to an exchange plan through premium assistance. “The rationale was that this disrupts the exchange risk pool, so I think the first question is does HHS really intend to discourage copay assistance or was that mostly focused on premium assistance? And then furthermore, it doesn’t really have any enforceability, so I think either way we’re going to need some more rulemaking or guidance if [HHS] actually intends to prohibit either premium or copay assistance,” Pearson tells AIS.

But some say HHS theoretically can’t ban the cards using the anti-kickback argument because not everyone in the program will qualify for a subsidy. “The reality is there’s just no way that it could be operationalized if they made any other decision,” observed Joel Owerbach, Pharm.D., vice president of health policy and strategy at
Alliance Life Sciences Consulting Group, during the Nov. 13, 2013, webinar “Health Insurance Marketplaces and Exchanges, Post-Launch: Where Do We Stand?”

“It would be absolutely impossible with the way the marketplace is set up for anyone…to know whether…a person had a federal subsidiary as part of the exchange,” explained Owerbach, who is the former chief pharmacy officer of Excellus BlueCross BlueShield. “It’s not like Medicare and it’s not like Medicaid where it’s uniform and if you’re Medicare, you’re a part of that particular program. It’s 70% to 75% of people in the program that will actually have a federal subsidy tax credit, so in essence the ruling would suggest, as we would suspect, that this is going to be more like [the] commercial [market] and therefore these coupons, copays and subsidies will be allowed.”

**Drug Companies Should Protect Themselves**

Meanwhile, pharmaceutical manufacturers that try to maintain brand loyalty through the cards should make sure they’re protected in their efforts to promote them in the exchanges, he advised. “I think that the bottom line is the legal departments for any of the companies just need to build a solid foundation from which the company can go ahead and from an opportunity perspective create and re-enhance the subsidies that are there,” said Owerbach. “So should there be any contrary guidance that backtracks from the Oct. 30, 2013, [letter], then at least any activity that a company has done has been done on good faith, based on the information that was available and based on the path that the company has set to make sure that the coupons and the subsidy levels are being designed and implemented in an appropriate way.”

“I think most of the drug companies are taking a wait and see approach,” weighs in Pearson. “From what we’re hearing, different legal counsels are assessing that information differently. I think some of them are feeling like even with the HHS letter, they would like an OIG decision before they accept the anti-kickback provision.”

As for the plans, “I think it will be a pretty significant issue if these coupons [are allowed] because people go where the money is, and if these coupons are out there, people are going to use them,” Roy Moore, senior director at Decision Resources Group, tells AIS. But Moore, who regularly monitors prescribing practices and payer coverage across a variety of therapeutic categories as an author of the firm’s *U.S. Physician & Payer Forum* reports, suggests that the impact will vary by class. For instance, in a recent survey of psychiatrists, Decision Resources learned that nearly all of the physicians expected to tell their patients about coupons if they are allowed in the exchanges, particularly for nonpreferred brand drugs like Abilify (aripiprazole). “A lot of these people weren’t insured before and there’s going to be sticker shock when they find out that they have to pay a $60 copay for a nonpreferred drug, so the physicians view these coupons as getting around that sticker shock,” he explains.
Biggest Plan Worry May Be Specialty Rx Cards

Moreover, where plans may be even less enthusiastic about the use of coupons is in specialty categories where they’ve done some tiering to prefer certain biologics, predicts Moore. WellPoint, Inc., which has several units operating on the exchanges, tells AIS that while it allows copay cards in all of its plans and benefits where not prohibited by law, there can be unintended consequences associated with their use, especially with specialty drugs. “The coupons and copay cards may drive a member to ask their prescriber for a drug that’s not the best option for them. In the case of specialty drugs, some of these drugs may not be meant for first-line therapy,” says Lynn Rossetto, Pharm.D., vice president of pharmacy clinical accounts. “Long-term and widespread use of the cards impact the ability of plans to offer the best premium value for customers.”

Regardless of whether HHS issues additional guidance, plans likely designed their drug benefits with the possibility in mind that the coupons would be allowed, suggests Pearson. “What we’ve seen in the exchanges is that plans are generally not covering all of the drugs, so they’re really taking drugs off the formulary where they can and that is especially focused on these copay cards where they may not think that they are going to be able to enforce the cost sharing,” she tells AIS.

Moore concurs. “A lot of plans went through the fire of Part D where if you had too rich of a benefit you got burned with adverse selection, so we see them being more conservative this time,” he says.

Plans Continue to Weigh Options Around Specialty Rx Coupons

As plan sponsors seek new ways to contain rising specialty drug costs, with particular emphasis on increased formulary management, one area that continues to generate a lot of buzz but little action from health plans and PBMs is specialty drug coupons. When asked for the second year in a row if they are considering or had deployed any strategies to curb the use of widely available discount programs that may hinder the preferring of specialty products, many indicated that they were evaluating strategies.

Based on the success of a copay coupon elimination pilot launched in 2013 covering six medications chosen because of the availability of lower cost, therapeutically equivalent options, UnitedHealth Group’s UnitedHealthcare unit has expanded the program to cover an additional 25 medications as of Jan. 1, 2014. The eliminations impact less than 1% of UnitedHealthcare members currently taking one of these drugs, and the action does not apply to needs-based assistance programs.

While it did not take as calculated an approach, Express Scripts Holding Co. updated its National Preferred Formulary by removing 48 products based on recom-
mendations from its pharmacy and therapeutics committee “to ensure clinical appropriateness.” Most of those agents were linked to copay coupons, and included several specialty drugs, such as the new oral rheumatoid arthritis drug Xeljanz (tofacitinib) as well as older, more commonly used agents such as the multiple sclerosis treatment Betaseron (interferon beta-1b). Express Scripts’ Adam Kautzner, Pharm.D., senior director of drug trend and formulary solutions, says clients are asking the PBM to apply this approach to other high cost and increasingly competitive drugs, both traditional and specialty, in 2015 and beyond. Meanwhile, Express Scripts client BlueCross BlueShield of Tennessee tells AIS it has considered the value of limiting specialty drug coupons but has not taken steps to implement anything at this point.

“Specialty coupons and patient assistance programs can be effective programs to help members offset high out-of-pocket costs, but coupon use should not circumvent existing utilization management programs, care management programs or formulary management strategies,” observed Prime Therapeutics LLC Senior Director of Health Outcomes Steve Johnson in January 2014. While Prime currently relies on prior authorization and step therapy as the primary modes of reducing the utilization of nonpreferred specialty agents, it will “continue to evaluate strategies to promote preferred specialty drugs while considering the effect on prescription abandonment and adherence,” says Johnson.

“The pharmaceutical industry needs to understand the fact that pushing all what they manufacture by all means is no more a marketing strategy that will be tolerated by the health care provider/payer community,” weighs in Mesfin Tegenu, R.Ph., president of PerformRx, LLC, a PBM that is a fully owned subsidiary of the AmeriHealth Caritas Family of Companies. To deter the use of coupons for nonpreferred or nonformulary drug products, PerformRx says it will implement programs such as “increasing the differential for the nonpreferred products to the point that the financial consequences of using a coupon make the transaction cost prohibitive to the member (the after-coupon price is still higher than the cost of the preferred agent) and financially neutral to the health plan (post-coupon cost is the same as the cost of the preferred agent),” he explains in a January 2014 email to AIS.

MedImpact Healthcare Systems, Inc. adds that it supports clients who believe the use of drug coupons on nonpreferred specialty medications eliminates the incentive for patients to move to a preferred drug, and is considering the exclusion of some nonpreferred specialty products where clinically equivalent therapeutic alternatives exist.

**Some Will Rely on PA, Site of Care**

Declining to comment on the coupon issue, Aetna Inc. says it is directing its specialty pharmacy efforts more to “site of care and sourcing of pharmaceuticals to the most cost-effective providers,” adds Edmund Pezalla, M.D., national medical director for pharmacy policy and strategy.
While OmedaRx (formerly RegenceRx) is concerned about appropriate use of certain high-cost specialty agents, “we have prior authorization that’s necessary and in some cases we would require the use of one product before we would cover another product, so under those circumstances the copay cards aren’t really going to impact our utilization,” asserts Sean Karbowicz, Pharm.D., director of clinical evaluation and policy. “At the same time, these medications are very expensive and if there are programs that make them less costly for people who truly need them and particularly [for] indigent patients, then we want to support and do what we can to make sure these medications are available and affordable. It’s a balanced picture, I think.”

Prime’s Copay Offset Support Reaps Big Savings for Members

With coupons now available for hundreds of specialty and traditional nonspecialty drugs, and stakeholders divided on their opinions of them, many PBMs and specialty pharmacies are trying to squelch the usage of them. But Prime Therapeutics Specialty Pharmacy actually is encouraging their use for specialty drugs that do not have cheaper generic alternatives when members go through the proper utilization management programs. And according to Prime, its efforts, which also include getting members into patient-assistance programs (PAPs), are producing real savings for enrollees.

The company studied 264,801 Prime Therapeutics Specialty Pharmacy prescription claims for 37,890 members totaling $911,779,674 and found the following information:

- **Prime Specialty Pharmacy helped 19,862 members save $21,234,246 through the use of manufacturer coupons and PAPs.**
- **The total savings of more than $21 million was 60.2% of the member share.**
- **Copay offsets were applied to the member share of 117,330 claims.**
- **The average per-member per-year savings for people who took advantage of either coupons or PAPs was $1,069.**

According to Pat Gleason, Pharm.D., director of health outcomes for Prime, “We were surprised at the prevalence and amount of copay offset opportunity to our Prime Therapeutics Specialty Pharmacy members. We did not expect we would...secure more than $21 million in copay offsets and that more than half (52%) of our members using Prime Therapeutics Specialty Pharmacy would benefit from some amount of copay offset. Specifically, we were surprised that the copay offset programs covered 60% of the member cost share at an average of $1,069 per member per year among those who received any copay offset. Also, we were surprised that among 117,330 dispensed specialty prescriptions for which a copay offset was found, more than 57.4% had greater than $50 member cost share prior to the copay offset, but after applying the copay offset, only 2.8% had greater than $50 member cost share. That is a dramatic reduction in proportion of patients paying more than $50 a month for their specialty drug.”
Prime Helps Members Sign Up

Members can bring in coupons to Prime Therapeutics Specialty Pharmacy or register ahead of time for a PAP, “and our team is able to tap into the program on behalf of the member. If the member is unaware of copay offset programs, Prime Therapeutics Specialty Pharmacy staff helps to identify, pursue and apply a coupon or PAP to alleviate out of pocket expense for the member.”

The specialty pharmacy, he tells AIS, wants “to help people get the medicine they need to feel better and live well, …[so] every member expressing financial hardship is evaluated for copay offset opportunities. Prime Therapeutics Specialty Pharmacy routinely reaches out to copay offset programs to verify if our member is currently active with any; if not, Prime Therapeutics Specialty Pharmacy takes steps to either apply on the member’s behalf and/or assist the member with enrolling in the copay offset programs.”

Because Prime Therapeutics Specialty Pharmacy “has established relationships with manufacturers/foundations offering patient copay offset programs,” signing up for programs goes fairly smoothly, Gleason says. The company “has access to copay cards from the manufacturers which may be applied to members’ active accounts, or we may access provider portals to apply on members’ behalf.” In situations where members themselves must call to enroll in a PAP, “most approvals are granted the same day; no delay in prescription fills means no delay in therapy.”

The specialty pharmacy has four full-time employees “whose daily focus is to research and process patient assistance funding. Additionally, our member care associates engage members about copay offset programs while setting up orders, and our billing department also routes questions to these trained staff members to ensure the opportunity to facilitate patient assistance is pursued in the best interest of our members.” However, he says, “no reimbursement of time or cost to access these copay offset programs exists.”

Prime applies various specialty drug management strategies — including prior authorization, step therapy and quantity limits — to products under both the pharmacy and medical benefits. “These strategies are deployed before copay offset programs are applied,” Gleason explains.

He adds, “We do not have information on whether a member was limited in the amount of coupons they received for the product. What we do know is our members do not disrupt therapy due to exhausting PAP benefits. We offer alternative payment arrangements to allow our members to budget for any additional out-of-pocket expenses.” 

◊
New Prime Data Show High Copay Card, PAP Use Among Autoimmune, MS Patients

A full year’s worth of new data on the prevalence of manufacturer-offered discount programs applied to specialty pharmacy claims in 2013 may help Prime Therapeutics LLC better inform plan sponsors about the importance of utilization management strategies to encourage the use of preferred products, especially in the autoimmune and multiple sclerosis (MS) categories.

According to research presented at the 2014 Pharmacy Benefit Management Institute Drug Benefit Conference, held Feb. 3-5, 2014, in Las Vegas, more than half of members using Prime Therapeutics Specialty Pharmacy in 2013 applied a manufacturer coupon or patient assistance program (PAP), resulting in savings of more than $21 million.

“Copay coupons can be inappropriate for many medicines when there are low cost generic alternatives available,” explained Patrick Gleason, Pharm.D., director of health outcomes, in a February 2014 interview with AIS. “However, copay coupons can be vitally important for specialty medicines due to the high costs and lack of generic alternatives. Therefore, we studied our claims data to gain a deeper understanding of how much couponing is out there and to what extent it is offsetting member share.”

Prime Therapeutics Specialty Pharmacy dispensed 264,801 specialty drug prescriptions for 37,890 members totaling $911,799,674 in 2013. These members represent approximately 45% of members utilizing specialty drugs throughout Prime’s commercial book of business. The study identified 19,862 members (52%) who received a copay offset, which resulted in $21,234,246 in savings for members, or 60.2% of the original member share ($35,297,162). Moreover, the PBM found that 117,330 of the prescriptions (44.3%) had a copay offset applied to the member share.

The PBM then analyzed copay coupon and PAP use by core therapeutic category. For example, 76,437 claims for autoimmune drugs were associated with a coupon or PAP for 12,425 members, resulting in a copay offset amount of $12,888,916. In other words, three-fourths of members’ spending on autoimmune drugs was offset by coupons and PAPs in 2013, explains Gleason. Similarly, 60% of member cost share in the MS category was offset by discount programs. “We didn’t expect it to be that high,” remarks Gleason in an interview with AIS. “That was enlightening for us.”

For the 117,330 prescriptions dispensed in 2013 by Prime Therapeutics Specialty Pharmacy with a copay offset, the company also sought to understand what the patient share was before and after the coupon/PAP was applied using two different cut points, $50 and $150. For example, 57.4% of prescriptions had a cost share above $50, but the use of coupons/PAPs drove that portion down to 2.8%. Likewise, 20.2% of prescriptions were associated with a cost share higher than $150 prior to the use of coupons, but that share dropped to 2% after discounts were applied.
Gleason explains that Prime chose those cut points because $50 is a typical preferred tier cost share, whereas a cost share of $150 or above is what Prime and other companies have found is when specialty therapies are more likely to be abandoned.

The study is a continuation of a previous analysis that looked at six months’ worth of specialty pharmacy claims data and determined that coupons and PAPs were applied to four out of 10 prescriptions going through Prime Therapeutics Specialty Pharmacy, resulting in about $10.6 million in member savings.

To conduct the six-month and full-year analyses, Prime created a file for each prescription that contained detailed information on the pharmaceutical manufacturer coupon or PAP amount reimbursed to offset member share. The file was then linked back to the PBM claim records to identify Prime Therapeutics Specialty Pharmacy-only claims that were final paid claims.

Data May Encourage Hard Edits

Now armed with a full year’s worth of data, Prime is better equipped to discuss the impact of coupons with its 13 Blue Cross and Blue Shield plan owners and self-insured employer group clients. “It’s important to manage drug classes — autoimmune and MS in particular [which are rich with options] — when coupons can, if not used appropriately, overwhelm or circumvent the use of preferred products,” Gleason tells AIS. “This study helps us show decision makers the volume of coupon [use] in order to encourage step therapy and prior authorization and drive to that preferred product.”

<table>
<thead>
<tr>
<th>Core Category</th>
<th>Coupon/PAP Claims</th>
<th>Coupon/PAP Members†</th>
<th>Coupon/PAP Amount</th>
<th>% of Member Cost Share Offset by Coupons/PAP</th>
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</thead>
<tbody>
<tr>
<td>Autoimmune</td>
<td>76,437</td>
<td>12,425</td>
<td>$12,888,916</td>
<td>76.8%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>31,513</td>
<td>5,542</td>
<td>$6,493,159</td>
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<tr>
<td>Cancer-Oral</td>
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<td>392</td>
<td>$699,635</td>
<td>41.2%</td>
</tr>
<tr>
<td>Growth Hormones</td>
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<td>606</td>
<td>$384,820</td>
<td>15.6%</td>
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<tr>
<td>Hepatitis C</td>
<td>1,805</td>
<td>311</td>
<td>$381,732</td>
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<td>Cystic Fibrosis</td>
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<td>222</td>
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<td>12</td>
<td>11</td>
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<td>1.2%</td>
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<tr>
<td>High Cost Others</td>
<td>587</td>
<td>172</td>
<td>$111,600</td>
<td>13.9%</td>
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<tr>
<td>Hemophilia</td>
<td>6</td>
<td>3</td>
<td>$1,440</td>
<td>3.6%</td>
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<tr>
<td>Others*</td>
<td>1356</td>
<td>193</td>
<td>$171,402</td>
<td>21.6%/Ranges 0.1%-74.2%</td>
</tr>
<tr>
<td>Overall</td>
<td>117,330</td>
<td>19,862</td>
<td>$21,234,246</td>
<td>60.2%/Ranges 0.1%-78.5%</td>
</tr>
</tbody>
</table>

* Others include pulmonary hypertension, lung disorders, immune globulins, enzyme deficiencies, HIV, cancer-injectable, and anticoagulants.
† Members column does not sum due to some members using drugs in multiple core categories.

SOURCE: Prime Therapeutics LLC. Contact Karen Lyons at klyons@primetherapeutics.com for more information.
If plans choose not to employ hard edits to drive to the preferred product, Gleason says Prime will explore two other avenues:

(1) **Discuss therapeutic interchange with the patient.** As new therapy starts for autoimmune or MS drugs come into Prime Therapeutics Specialty Pharmacy, the pharmacist will make an attempt to therapeutically interchange products by asking the patient to use the preferred product, and contact the physician to request a switch to the preferred product. “This is a much softer approach,” says Gleason.

(2) **Allow the use of coupons for nonpreferred agents.** If patients and/or physicians choose not to use the preferred agent, then Prime will “optimize” the use of coupons. “From our perspective, we want patients to get medications that they need to feel better and live well,” he adds.

Gleason says that Prime is aware of harder approaches being taken by UnitedHealthcare, which in 2013 began blocking the use of coupons on select agents through its network specialty pharmacies, and Express Scripts Holding Co., which eliminated several specialty products from its National Preferred Formulary for 2014. “We are working to understanding this approach better and consulting with our health plans to determine if they’d like to implement those types of programs in the future,” says Gleason.

And just because other classes show less than 50% of cost share being offset by coupons doesn’t mean those numbers will stay low. “We expect more manufacturers to be offering coupons in these other classes in which the share appears to be smaller,” he adds, pointing to oral cancer as an example. “It helps to move the health plan to make a decision about further managing the class when they see how big couponing is in the autoimmune and multiple sclerosis classes, for example.”

**With Retail Strategy, UnitedHealthcare Draws New Line in Sand for Copay Cards**

When it comes to curbing the use of manufacturer-offered copay coupons and other copay offset programs, health plans and PBMs have commonly enlarged copay differentials, applied utilization management and, in some more recent cases, excluded select brands from formularies when there are lower-cost options available. But UnitedHealthcare is trying a more comprehensive — and some say more cumbersome — approach by attempting to block the use of copay coupons at the retail level.

Through the new “retail coupon initiative,” UnitedHealthcare will work with its network retail pharmacies to discontinue the use of copay coupons as of July 1, 2014, according to a March 4, 2014, update to its website for brokers. The change applies to fully insured and self-funded customers using UnitedHealthcare’s Advantage and Traditional Prescription Drug Lists, the SignatureValue Formulary and OptumRx direct business.
But it remains unclear how many pharmacies will participate in the initiative and whether they will receive any kind of incentive to do so. Adam Fein, Ph.D., president of Pembroke Consulting, Inc., warns that the insurer’s new strategy “will be difficult to implement with its current retail network.” Some pharmacies, particularly the large chains, may not be willing to cooperate, he suggests.

When contacted to provide further details on how the program will work, spokesperson Lynne High issued the following statement: “Our goal at UnitedHealthcare is to ensure consumers have access to affordable health care. That includes helping our members find the lowest-cost option for their prescription drugs. Use of manufacturer copayment coupons can drive patients away from lower cost, therapeutically equivalent alternatives and can significantly increase overall healthcare costs.”

United Kicks Coupons to the Curb

In the broker notice, the insurer said it plans to notify members affected by the change via mail by June, will communicate the formulary updates to physicians and will work with retail pharmacies to inform members of the change and alert them to less expensive medication alternatives.

“We provide our members with several options including helping them find the therapeutically equivalent generic drug at a significantly lower cost; offering the convenience of a mail-service program; and covering $4 retail pharmacy copay programs,” added High. “Assistance from customer care representatives is available to members who can call the number on the back of their ID card or visit myuhc.com.”

The decision to block copay coupons at the retail level follows UnitedHealthcare’s successful strategy to limit the use of manufacturer-offered coupons on specialty drugs through its network specialty pharmacies. The insurer began that initiative in 2013, and expanded the list of blocked coupon programs from six to more than 30 specialty drugs for 2014.

UnitedHealthcare’s new strategy represents “the largest step taken to ban the use of such coupons...and others may follow suit,” observed Avalere Health LLC Vice President Sandy Robinson in a March 27, 2014, blog post.

Program May Mean More Work for Providers

But Robinson pointed out that the new program may create a burden for hospitals, physician offices and pharmacies to “conduct additional benefit investigations and coverage research to support patients insured by UHC’s member plans that will no longer accept retail copay coupons.”

At the same time, a decrease in sales of brand-name drugs with high copay coupon utilization may lead manufacturers to “consider adjusting patient support programs to help guide patients through the manual rebate submission to encourage ongoing medication adherence,” she suggested.
The change will also pose a quandary for members. “Patients who rely on copay coupon support for affordable access to medication will need to decide whether they will move from current treatment to a lower-cost alternative or face the increased administrative burden of manual adjudication of copay coupons and back-end reimbursement,” added Robinson. “The latter will likely prompt discussion within the patient access community as advocacy organizations work to find ways to submit initial payment and then be reimbursed by the manufacturer on beneficiaries’ behalf.”

**Blocking Cards Could Link to Narrow Networks**

“Looking forward, copay cards could shape preferred and limited pharmacy networks,” predicts Fein. “Today, a pharmacy’s participation in a payer’s narrow network is based primarily on the pharmacy’s willingness to accept reduced reimbursements.”

He adds, “PBMs are likely to consider additional selection criteria linked to a pharmacy’s compliance with a payer’s benefit management plan. For example, a PBM could select only pharmacies with higher generic substitution rates or a greater willingness to block copay cards.”

**As Copay Coupons Rise, Payers Should Eye Drugmakers’ Efforts to Enrich Offsets**

As health plans and PBMs consider how to address manufacturer-offered copay cards and other discounts on brand-name drugs — whether by encouraging their use among members, blocking the coupons or taking a more targeted approach — payers should keep a close watch on pharmaceutical manufacturers’ attempts to refine these programs to match competitors and gain market share. Keeping abreast of changes in specialty categories like multiple sclerosis (MS) and rheumatoid arthritis (RA), which are rich with therapeutic options, may be especially important as those categories experience high copay offset utilization, suggests Zitter Health Insights’ Co-Pay Offset Monitor.

In the 2014 industry report, the research firm observed 561 copay offset programs being offered for 708 brand-name drugs as of winter 2014, compared with 531 programs for 650 brands in summer 2013. Of those 708 brand-name drugs with copay offset programs, 20% are for branded biologic drugs, and of those biologics, 60% are focused on chronic diseases, reports Zitter. A copay offset program can be applied to more than one brand, and vice versa, points out the firm.

Zitter conducted the research from July through December 2013. A copay offset program refers to a manufacturer-sponsored copay program for branded pharmaceutical products directed at the commercially insured population, clarifies the research firm. This is separate from a patient assistance program (PAP), which is a manufacturer-sponsored copay assistance nonprofit foundation or program to help uninsured patients (or those denied coverage by their commercial plans) who meet specific finan-
cial eligibility criteria, or a foundational assistance program, which is an independent nonprofit foundation or program to help underinsured patients who meet specific financial eligibility requirements.

Within those 30 additional programs identified in the second half of 2013, Zitter analyst Sneha Shah suggests that there may have been a shift of multiple brands in single copay programs splitting into multiple programs, or new programs accompanying the introduction of new drugs. “What was really notable was when a specialty drug was introduced to the market, then it usually was paired with a copay program,” Shah told AIS in March 2014.

She adds that she wouldn’t be surprised to see that 20% portion of branded biologics grow as more specialty drugs are introduced. “Cost sharing is not going to go away, especially as specialty medications are becoming the future,” she remarks. “These medications are expensive and tools like copay offset programs and other assistance programs are going to increase. So if specialty medications are becoming the future, then there has to be an integrated approach to tackle this problem, where patients can actually access those medications and in that case copay offset and [other discount] programs would work.”

The company identified RA as the category with the highest copay offset program utilization, followed by psoriasis and MS. These findings are consistent with a recent internal analysis performed by Prime Therapeutics LLC that showed high copay coupon/PAP use among autoimmune and MS patients. “A lot of these programs have zero-dollar copays or patients pay only $5 or $10,” observes Shah. “They are quite rich in benefits, so I am not surprised that utilization is so high.” Of a study sample representing 25% of national specialty pharmacy claims, roughly 55% of the 678,346 eligible RA prescriptions processed during the third quarter of 2013 were associated with a copay offset program. Meanwhile, 27.8% of the 342,541 MS prescriptions were supported by a copay offset program in the same quarter.

Within the MS category, however, utilization varied wildly over a year and a half. For example, both Copaxone (glatiramer acetate) and Aubagio (teriflunomide) experienced a “sharp nosedive” but eventually “normalized,” says Shah.

**Drug Companies Tweak Copay Programs**

What accounts for such drastic swings in utilization? Shah explains that in the first quarter of 2012, Copaxone maker Teva Pharmaceuticals Industries Ltd. had dramatically increased prices and the drug was removed from most formularies. Teva swiftly recovered by enhancing access to the medication by increasing the annual maximum copay offset from $6,000 to $12,000, she says. Meanwhile, when Genzyme Corp.’s oral agent Aubagio was introduced in the fourth quarter of 2012, it came with a three-month free trial and $35 copays after that. When utilization dipped in the following quarter, the drugmaker also enhanced its copay offset program so that patients would
pay only $10. Shah points out that most of these offers have expiration dates, and the drugmaker has the freedom to change the terms of the offer at any time.

Moreover, the firm observed that debit cards account for about 11% of biologics copay offset programs, where none exist for traditional drugs. Shah suggests that’s because the benefits offered by copay offset programs for specialty drugs tend to be “richer” than for traditional therapies. Other forms of copay offset offered by specialty pharmaceutical manufacturers include coupons/cards (68%), reimbursement accounts (16%) and the less frequently used mobile coupon, buy-and-bill and direct programs. In fact, only one program observed by Zitter offered a mobile coupon in combination with a copay card, whereas those discounts are more frequently seen in the small molecule realm (3% of 446 programs), adds Shah.

### Co-Pay Offset Program Trended Script Utilization for Multiple Sclerosis Products Through Specialty Pharmacy Provider

*Program Scripts/Eligible Scripts With a Co-Pay*

**Source:** Zitter Health Insights' Co-Pay Offset Monitor, Winter 2014. Contact Michala Jeberg at mjeberg@zitter.com for more information.
Appendix B: Zitter Health Insights’ Co-Pay Offset Monitor

**Key Findings**

Rheumatoid Arthritis enjoys the highest co-pay program utilization when compared to other therapeutic areas.

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**Co-Pay Program Utilization – between TAs**

**Co-pay Program Utilization Trending Data**

- Oral Oncology (n = 77261)
- Multiple Sclerosis (n = 432868)
- HCV Mean (n = 92229)
- Pulmonary Arterial Hypertension (n = 71844)
- HIV Mean (n = 242217)
- Rheumatoid Arthritis (n = 725,350)

Recent introduction of Sovaldi.

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*Data based on average of 525,000 scripts processed quarterly through specialty pharmacies, representing 25% of national specialty pharmacy claims.*
Key Findings
60% of biologic brands with co-pay offset programs are targeted for chronic conditions.

The Prevalence of Co-Pay Offset Programs

Increase of 2% in co-pay programs targeted for Biologics brands from Winter 2013 analysis.

Brands Per Condition Type

- Acute: Orphan Biologic: 3%
- Acute: Life Enhancing Biologic: 7%
- Acute: Biologic: 27%
- Chronic: Life Threatening Biologic: 60%
- Chronic: Orphan Biologic
- Chronic: Biologic

Percentage of Non-biologics Brands vs. Biologic Brands

n = 518 Brands with Co-Pay Offset Program
### Key Findings
Some brands offer savings on additional services to ease patient access to drugs

<table>
<thead>
<tr>
<th>Co-pay Offset Program</th>
<th>Add-on Benefit Details</th>
</tr>
</thead>
</table>
| **HUMIRA PROTECTION PLAN** | - Maximum savings of $25 for DMARD prescription per month  
- Only drug in the category offering this benefit |
| **GILENYA (fingolimod)** | - The Gilenya Medical Co-pay Support Program  
- Covers for initial assessments/exams or for First Dose Observation (FDO) |
| **Welchol Savings Card** | - The Welchol Savings Card  
- $25 co-pay for a 30-day supply **plus** $10 off branded or generic statin and/or metformin |
Health Plans Analyzing Strategies Around Co-pay Card Use

- PerformRx, LLC working on cost and pricing strategies to deter use of co-pay cards
- Prime Therapeutics and OmedaRx to allow using co-pay cards when “appropriate”

Key Findings
Payers and PBMs have taken very different stands on implementing co-pay policies; where Express Scripts have very restrictive strategies, Prime Therapeutics consider them helpful when appropriate.

United Healthcare expanded their co-pay coupon elimination pilot program launched in 2013 with 6 medications to further cover 25 medications in 2014.

PerformRx, LLC to implement programs that will increase the after-coupon price of non-preferred agent when compared to preferred agent for patients to deter use of co-pay cards. Post coupon cost of non-preferred agent will be same as preferred.

MedImpact Healthcare Systems, Inc. considering exclusion of non-preferred specialty products when clinically equivalent alternative exists.

BlueCross BlueShield of Tennessee has considered the idea of limiting co-pay coupon use. However, no strategies are still in place.

OmedaRx has PA policies in place and expect co-pay cards to not impact utilization. However, when appropriate OmedaRx is ready to do what is necessary to make medications accessible and affordable to patients.

Prime Therapeutics LLC published a study in October 2013 on how co-pay coupons helped 4 in 10 members save on their drug costs. Prime Therapeutics manage healthcare costs by identifying co-pay assistance programs when appropriate.

*Prime Therapeutics study shows 4 in 10 specialty pharmacy members saved with co-pay coupons and patient assistance programs (October 3, 2013)
Appendix C: Prime Position: Manufacturer Copayment Coupons


**Prime Position**

**Manufacturer Copayment Coupons**

**Coupons are a powerful savings tool**

Clipping coupons is one way thrifty people make their money go farther. And when times are tight, coupon use soars. The number of coupons redeemed for various products grew 35 percent between 2007 and 2011. Coupon savings peaked at $4.6 billion in 2011, yet consumers continue to use coupons to save at rates nearly 60 percent higher than before the recession.\(^1,2\)

Coupons exist to increase consumers’ awareness of products or services. They can entice shoppers to try a new product or purchase something they wouldn’t ordinarily buy, thus changing their product preferences and purchasing habits. It is precisely because coupons have the power to change consumer attitudes and behaviors that drug manufacturers issue them for brand name medications.

**What’s wrong with saving money?**

Coupons themselves are not necessarily bad — and neither is the desire to save money. In fact, coupons, waivers and other financial incentives are used by payers and PBMs to help members afford costly treatments and encourage them to make cost-saving choices.

But some drug manufacturers’ coupons are clearly designed to increase sales of brand-name products, even though less expensive options exist. Members may not know that using these coupons can increase costs for their benefit plan. Since most people with insurance do not pay the full cost of their drugs, it is usually the plan sponsor who ends up paying the price for bad coupon use.

**How drug manufacturer coupons work**

Under a typical pharmacy benefit, members must pay a set amount (copayment or coinsurance) for every prescription. Any charges beyond the initial copayment are covered by the plan sponsor, usually an employer or insurance company. Manufacturer coupons reduce the copayment, decreasing members’ out-of-pocket costs. This is good when it helps make expensive specialty drugs more affordable and in other cases where there are few or no cheaper generic alternatives available.

But some coupons encourage negative behavior, such as using a brand name drug when a cheaper generic version exists. Coupons like this drive up benefit costs for everyone, because the plan must cover the full cost of the more expensive drug. When a generic is used instead of a brand name drug, the member and the plan both have the opportunity to save (Figure 1).

In another common scenario, a manufacturer’s coupon eliminates the cost difference between a plan’s preferred and non-preferred brand-name drugs. This practice undercuts the cost saving power of benefit plan design and can even end up affecting drug prices.

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\(^1\) Coupons are a powerful savings tool
\(^2\) Good coupon use helps members pay for treatments they couldn’t otherwise afford (high-cost specialty medicines, for example).

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**Fig. 1 Brand vs. generic drug costs, by payer**

<table>
<thead>
<tr>
<th>Total cost = (plan + member)</th>
<th>$210</th>
<th>$30</th>
<th>$190</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand</strong></td>
<td>$30</td>
<td>$20</td>
<td>$120</td>
</tr>
<tr>
<td><strong>Generic</strong></td>
<td>$180</td>
<td>$20</td>
<td>$180</td>
</tr>
<tr>
<td><strong>Brand (w/coupon)</strong></td>
<td>$180</td>
<td>$20</td>
<td></td>
</tr>
</tbody>
</table>

- Member cost (copay)
- Manufacturer cost (coupon)
- Plan cost
- Potentially avoidable plan cost
Drug coupon use has grown
More and more pharmaceutical companies are using coupons to lure people away from lower-priced alternatives. According to IMS Health, the use of drug copay cards and coupons tripled between 2006 and 2011.3 Coupon clearinghouse NCH reports consumers’ use of coupons for over-the-counter and prescription medicines grew 7 and 6 percent in 2012 and 2013.1,2 This is in spite of the fact that coupons are not legal for use under Medicare Part D, whose members are the largest users of prescription medicines.

Strategies to trim negative coupon use
Coupons are promoted as a way to help consumers save on drugs, but for some the true intent is to increase sales of brand-name products. Employers and insurers must work together to educate members about the true cost of these “savings” and limit inappropriate coupon use.

Recommended benefit management strategies include:
- **Education** – Providing information and education about the hidden cost of drug coupons
- **Formulary management** – Targeted products can be removed from the formulary
- **Benefit design** – Increasing copay tier differentials substantially enough (or assessing fees to cover the difference of brand to generic) to lessen the use of undesired coupons
- **Utilization management** – Step therapy or prior authorization for targeted drugs prevents automatic processing of coupon-available products and allows time for review
- **Benefit exclusion** – Targeted products and categories can be excluded from coverage

These options can be viewed on a spectrum from lightly managed to aggressively managed. Aggressive management offers a greater ability to limit negative coupon use, but it is also likely to result in more member disruption.

While addressing the cost impact of coupons is important, helping members get the medicine they need to feel better and live well is critical. That’s why all of Prime Therapeutics’ recommended benefit strategies put member safety and clinical appropriateness first.
Helping members afford high cost drugs
The high cost of specialty medicines has been shown to negatively affect members’ adherence to their medicines. That’s why Prime helps members take advantage of specialty manufacturer coupons when it makes sense and supports our formulary preferences. In 2013, Prime helped members save more than $21.2 million on high-cost, specialty medicines by helping them secure these cost-reducing specialty copay offsets.

With specialty drug costs expected to rise to 50 percent of commercially insured total drug costs by 2018, coupons can be vitally important. But negative coupon use can cost plan sponsors money. Walking the fine line between “good” and “bad” coupon use can be challenging. But Prime has the data and expertise to build thoughtful strategies that effectively limit inappropriate coupon use and help to reduce its effect on overall health care costs.

1 2012 Coupon Trends. NCH Marketing Services, Inc. Available at https://www2.nchmarketing.com/ResourceCenter/couponknowledgestream4_ektid7687.aspx
Appendix D: HHS and CMS Guidance on Qualified Health Plans (QHPs)

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

October 30, 2013

The Honorable Jim McDermott
U.S. House of Representatives
Washington, DC 20515

Dear Representative McDermott:

Thank you for your letter regarding whether qualified health plans (QHPs) are considered federal health care programs under section 1128B of the Social Security Act. Section 1128B(f) of the Social Security Act defines "Federal health care program" as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government…or any State health care program….”

The Department of Health and Human Services does not consider QHPs, other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal health care programs. This includes the State-based and Federally-facilitated Marketplaces; the cost-sharing reductions and advance payments of the premium tax credit; Navigators for the Federally-facilitated Marketplaces and other federally funded consumer assistance programs; consumer-oriented and operated health insurance plans; and the risk adjustment, reinsurance, and risk corridors programs. This conclusion was based upon a careful review of the definition of “Federal health care program” and an assessment of the various aspects of each program under Title I of the Affordable Care Act and consultation with the Department of Justice.

The Department is taking strong measures to protect consumers and to ensure robust oversight of these critical Affordable Care Act programs. For example, on June 19, 2013, the Department proposed an oversight regulation governing these programs entitled Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37032). On August 30, 2013, the Department finalized the first set of compliance standards from that proposed rule in a final rule entitled Program Integrity: Exchange, SHOP, and Eligibility Appeals (78 FR 54070). The oversight provisions in this rule include requirements for decertification of QHPs and the imposition of civil money penalties against non-compliant issuers who have plans in the Federally-facilitated Marketplace.

In addition to these oversight provisions, the OIG has jurisdiction, under the Inspector General Act of 1978 (5 U.S.C. appx.), to audit, investigate, and evaluate the HHS-administered programs in Title I of the Affordable Care Act. Further, section 1313 of the Affordable Care Act authorizes HHS and the OIG to investigate the “affairs of an Exchange.” Congress also expressly provided that the False Claim Act applies to any “payments made by through, or in connection with an Exchange if the payments include Federal funds.” Finally, depending on the specific conduct in question, there may be additional federal and state criminal or civil
Q: Are third party payors permitted to make premium payments to health insurance issuers for qualified health plans on behalf of enrolled individuals?

A: The Department of Health and Human Services (HHS) has broad authority to regulate the Federal and State Marketplaces (e.g., section 1321(a) of the Affordable Care Act). It has been suggested that hospitals, other healthcare providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third party payments. HHS intends to monitor this practice and to take appropriate action, if necessary.
Appendix E: HHS and CMS Guidance on Patient Assistance Programs (PAPs)

Federal Register / Vol. 70, No. 224 / Tuesday, November 22, 2005 / Notices 70623

it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: November 14, 2005.
Jeffrey Shuren,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 2005N–0343]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Elsewhere in this issue of the Federal Register, FDA is publishing a notice announcing an opportunity for public comment on this collection of information. Since this collection received emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing that notice.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 1, 2005 (70 FR 52108), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0571. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: November 14, 2005.
Jeffrey Shuren,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 12, 2005, 9 a.m.–5 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Monday, December 12, from 9 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–369–6048 on December 12 and providing the following information: Leader’s Name: Dr. Geoffrey Evans. Password: ACCV.

Agenda: The agenda items for the December meeting will include, but are not limited to: A summary of the U.S. Court of Federal Claims’ 18th Judicial Conference; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail clee@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HHS, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail clee@hrsa.gov.

Dated: November 15, 2005.
Tina M. Cheatham,
Director, Division of Policy Review and Coordination.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Inspector General
Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This Federal Register notice sets forth the recently issued OIG Special Advisory Bulletin addressing patient assistance programs for Medicare Part D enrollees.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619–0335.


I. Introduction

Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means.
who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program. Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations (such as, for example, patient advocacy and support organizations) without regard to any specific donor or industry interests.

Many pharmaceutical manufacturers have historically sponsored PAPs that assist patients whose outpatient prescription drugs are not covered by an insurance program (including some Medicare beneficiaries), in obtaining the manufacturer’s products for free or at greatly reduced cost. Beginning on January 1, 2006, Medicare Part D will offer Medicare beneficiaries who elect to enroll broad coverage for outpatient prescription drugs. Accordingly, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria. Part D enrollees will incur cost-sharing obligations (including deductibles and copayments), although many low-income beneficiaries will qualify for subsidies that will reduce or eliminate their financial obligations.2

Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy. OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the anti-kickback statute or other laws.3 We have been asked whether the anti-kickback statute will be implicated if pharmaceutical manufacturer PAPs continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by PAPs, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe useful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.

Given the importance of ensuring continued access to drugs for beneficiaries of limited means and the expedited time frame for implementation of the Part D benefit, we are issuing this Special Advisory Bulletin to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse. This Special Advisory Bulletin draws on the government’s prior fraud and abuse guidance and enforcement experience. However, because the Part D benefit has not yet begun, and any assessment of fraud and abuse is necessarily speculative, this Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices. At the outset, it is important to note the following:

• PAPs need not disenroll all Medicare beneficiaries from their existing PAPs to be compliant with the fraud and abuse laws. Enrollment in Part D is voluntary; therefore, existing PAPs may continue to provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D. The Centers for Medicare & Medicaid Services (CMS) anticipates instituting procedures that will help PAPs determine if PAP clients have enrolled in Part D.

• Occasional, inadvertent cost-sharing subsidies provided by a pharmaceutical manufacturer PAP to a Part D enrollee should not be problematic under the anti-kickback statute (e.g., where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D).

• Nothing in the Part D program or in any OIG laws or regulations prevents pharmaceutical manufacturers or others from providing assistance (e.g., through cash subsidies or free drugs) to uninsured patients. Nothing in this Bulletin impacts programs that assist uninsured patients.

• Nothing in this guidance should be construed as preventing pharmacies from waiving cost-sharing amounts owed by a Medicare beneficiary on the basis of a good faith, individualized assessment of the patient’s financial need (or failure of reasonable collection efforts), so long as the waiver is neither routine, nor advertised. Financial need-based waivers that meet these criteria have long been permitted.4 However, a pharmacy has not waived a cost-sharing amount if the amount has been paid to the pharmacy, in cash or in kind, by a pharmaceutical manufacturer (or its affiliates) and support organizations) without regard to any specific donor or industry interests.

1 For purposes of this Special Advisory Bulletin, a pharmaceutical manufacturer PAP includes any PAP that is directly or indirectly operated or controlled in any manner by a pharmaceutical manufacturer or its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)). Moreover, for purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded or controlled by a manufacturer or any of its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) to be a bona fide, independent charity, because interposition of the entity would not sever the nexus between the patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer (or its affiliates) and would provide subsidies only for the manufacturer’s products.

2 See 42 CFR 423.782.

3 This Bulletin focuses on the application of the Federal anti-kickback statute. Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here. Moreover, this Bulletin focuses on arrangements that involve pharmaceutical manufacturers directly or indirectly subsidizing Part D cost-sharing amounts. Programs that subsidize Part D premium amounts pose risks under the anti-kickback statute that are not addressed here. Similarly, PAPs established by health plans that subsidize cost-sharing or premium amounts under Part D raise different issues and may require a different analysis. While this Bulletin may provide some useful guidance for other kinds of PAP arrangements, such PAPs are not specifically considered here.

4 See, e.g., section 1128A(b)(6)(A) of the Act; OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, August 2002, http://oig.hhs.gov/oei/advisorybullets/SABGiftsandInducements.pdf; The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a safe harbor specifically incorporating these criteria for waivers of cost-sharing amounts for Part D drugs. Additionally, the safe harbor protects cost-sharing waivers offered to individuals who qualify for the low income subsidy, even if the waiver is not routine, and do not follow an individualized determination of financial need, provided they are not advertised. See Section 1860D–42(a)(5)(B) of MMA, codified at 42 U.S.C. 1320a–7(b)(3)(B)(ii).
third party (including, without limitation, a PAP).

II. The Federal Anti-Kickback Statute

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act), makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. OIG may also initiate administrative proceedings to exclude a provider, practitioner, or supplier, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries’ incentives to locate and use less expensive, equally effective drugs. It is impossible to predict with certainty the way in which abuse may occur in a new benefit program that is not yet operational. The following are illustrative examples of some types of abuse that may occur:

- Increased costs to the program. We are concerned that a manufacturer might use beneficiary cost-sharing subsidies, which benefit beneficiaries meet their TrOOP requirement, to increase the number of beneficiaries using the manufacturer’s product who reach the

Section addresses in turn: pharmaceutical manufacturer PAPs, independent charity PAPs, manufacturer PAPs that operate “outside of Part D”; “coalition model” PAPs, and bulk replacement programs.

A. Pharmaceutical Manufacturer PAPs

Analytically, pharmaceutical manufacturer PAPs raise two main issues in connection with the Part D program: (i) Whether subsidies they provide can count toward a Part D enrollee’s true out-of-pocket costs (known as the TrOOP); and (ii) whether the subsidies implicate the Federal anti-kickback statute.

As to the first issue, the Part D regulations make clear that beneficiaries may count toward their TrOOP assistance received from any source other than group health plans, other insurers and government funded health programs, and similar third party payment arrangements. The preamble to the Part D regulations explains that cost-sharing assistance furnished by a PAP, including a pharmaceutical manufacturer, will count toward a beneficiary’s TrOOP expenditures, even if the PAP does not comply with the fraud and abuse laws. This approach relieves beneficiaries of the financial risk of accepting assistance from an entity that may be improperly structured or operated. As to the second issue, the core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer’s product. Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs, we believe such subsidies for

- In some cases, a subsidy for Part D cost-sharing obligations provided by a pharmaceutical manufacturer may also implicate the prohibition on offering inducements to beneficiaries, as set forth in section 1128A(a)(5) of the Act, if the subsidy is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier, such as a physician or pharmacy. We have interpreted “provider, practitioner, or supplier” to exclude pharmaceutical manufacturers unless they also own or operate pharmacies, pharmaceutical benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. See Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, supra note 4.

- See 42 CFR 423.100; 42 CFR 423.464; 70 FR 4194, 4239 (January 28, 2005). We note that CMS is the proper agency to address questions about the mechanics of calculating TrOOP. In certain circumstances, knowing improper TrOOP calculations may give rise to liability under the False Claims Act. 31 U.S.C. 3729–33.

- See 70 FR 4194 at 4239.

- See, e.g., OIG Advisory Opinion Nos. 02–13 and 03–3 (unfavorable opinions involving proposals from pharmaceutical manufacturer PAPs to subsidize Part B cost-sharing amounts). We note that the cost and utilization management features of the Part B program, while important, do not sufficiently mitigate the risks.

- Some in the industry have asserted that cost-sharing subsidies for Part D drugs differ from cost-sharing subsidies for Part B drugs so long as the subsidies are given to patients who are in a Part D “coverage gap” (i.e., a benefit period during which the beneficiary pays 100% of the cost of the drugs). To support their position, they contend either that beneficiaries in the coverage gap are functionally “uninsured” or that the situation is comparable to providing free drugs to financially needy beneficiaries so long as no Federal health care program is billed for all or part of the drug, a practice we previously permitted in the context of Part B drugs. See OIG Advisory Opinion Nos. 02–13 and 03–3. Under Part D, a “coverage gap” is a period of insurance coverage. See CMS Frequently Asked Question ID 4855, http://questions.cms.hhs.gov/cbi-bin/cashhba/clg.php/enduser/std_adp.php?p_flag=4855 (regarding prescription drug benefit coordination of benefits and TrOOP). During the coverage gap, beneficiaries remain enrolled in their Part D plans and have a continuing obligation to pay Part D premiums. Part D plans continue to receive the monthly per-encounter direct subsidy from the Medicare program. Moreover, subsidies during the coverage gap are not like furnishing free drugs where no Federal health care program is billed. Sufficient spending during the coverage gap qualifies the beneficiary to reach the catastrophic coverage portion of the Part D benefit, at which point the Medicare program resumes payment for most of the costs of the beneficiary’s drugs. In this regard, the differences in the different structures of the Part B and Part D benefits are crucial to the analysis.
catastrophic benefit in any given coverage year and to hasten the point during the coverage year at which beneficiaries reach the catastrophic benefit. This is of particular import because Medicare will make cost-based payments during the catastrophic coverage benefit.12 We know from experience that cost-based reimbursement is inherently prone to abuse, including by vendors that sell products reimbursed on a cost basis. Similarly, we are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices. Inflated prices could have a “spillover” effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years,13 potentially resulting in higher costs to the Medicare program.

B. Independent Charity PAPs

Long-standing OIG guidance makes clear that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, bona fide charitable assistance programs.14 Under a properly structured program, donations from a pharmaceutical manufacturer to an independent, bona fide charity that provides cost-sharing subsidies for Part D drugs should raise few, if any, anti-kickback statute concerns, so long as:

(i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) exerts any direct or indirect influence or control over the charity or the subsidy program;

(ii) The charity awards assistance in a truly independent manner that ensures any link between the pharmaceutical manufacturer’s funding and the beneficiary (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);

(iii) The charity awards assistance without regard to the pharmaceutical manufacturer’s interests and without regard to the beneficiary’s choice of product, provider, practitioner, supplier, or Part D drug plan;

(iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and

(v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.16

Cost-sharing obligations, both for purposes of calculating TrOOP and for purposes of determining the amount of in-kind drug that equals the Part D cost-sharing amount owed.

15 We recognize that what constitutes an appropriate determination of financial need may vary depending on individual patient circumstances. We believe that independent charity PAPs should have flexibility to take into account relevant variables beyond income. For example, PAPs may choose to consider the local cost of living, a patient’s assets and expenses, a patient’s family size, and the scope and extent of a patient’s medical bills.

16 We have previously approved a bona fide independent charity PAP arrangement that included only limited reporting of aggregate data to donors in the form of monthly or less frequent reports containing aggregate data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category. See OIG Advisory Opinion No. 02–1. No individual patient information may be conveyed to donors. Moreover, neither patients nor donors may be informed of the donation made to the PAP by others, although, as required by Internal Revenue Service regulations, the PAP’s annual report and a list of donors may be publicly available. See OIG Advisory Opinion No. 04–15. Reporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the

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13 We have previously approved a bona fide independent charity PAP arrangement that included only limited reporting of aggregate data to donors in the form of monthly or less frequent reports containing aggregate data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category. See OIG Advisory Opinion No. 02–1. No individual patient information may be conveyed to donors. Moreover, neither patients nor donors may be informed of the donation made to the PAP by others, although, as required by Internal Revenue Service regulations, the PAP’s annual report and a list of donors may be publicly available. See OIG Advisory Opinion No. 04–15. Reporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the

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14 See 42 CFR 432.329. For purposes of calculating payments under catastrophic coverage, the cost of a beneficiary’s drug is based in part on the plan’s negotiated price (i.e., a price that is set by the plan based on negotiations with pharmaceutical manufacturers and pharmacies).
15 We recognize that what constitutes an appropriate determination of financial need may vary depending on individual patient circumstances. We believe that independent charity PAPs should have flexibility to take into account relevant variables beyond income. For example, PAPs may choose to consider the local cost of living, a patient’s assets and expenses, a patient’s family size, and the scope and extent of a patient’s medical bills.
Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.

We recognize that some bona fide independent charities reasonably focus their efforts on patients with particular diseases (such as cancer or diabetes) and that some of these charities permit donors to earmark their contributions generally for support of patients with a specific disease. In general, the fact that a pharmaceutical manufacturer’s donations are earmarked for one or more broad disease categories should not significantly raise the risk of abuse. However, we are concerned that, in some cases, charities may artfully define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor’s particular products. For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases. This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories, and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.

aggregate, related to the identity, amount, or nature of subsidized drugs.

17 For further guidance on establishing compliant independent charity PAPs, see OIG Advisory Opinion Nos. 04–15, 02–1, 98–17, and 97–1 (favorable opinions issued to bona fide, independent charities that accept industry funding).

18 Nothing in this Bulletin should be construed as preventing a charity from obtaining educational materials from donors that the donors generally make available to practitioners or the general public (e.g., clinical information about drug products).

We recognize that, in rare circumstances, there may only be one drug covered by Part D for the diseases in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category. In these unusual circumstances, the fact that a specific disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. Such a determination could only be made on a case-by-case basis after examining all of the applicable facts and circumstances, including the intent of the parties. We note that it would be important for the PAP program to cover additional products or manufacturers as they become available.


20 We note that our position that PAPs operating outside the Part D benefit should provide assistance for the remainder of the coverage year is consistent with our observation in several advisory opinions that manufacturers “may provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit.” In these circumstances, the beneficiary obtains drugs without using his or her Part D insurance benefit. Beginning when a beneficiary’s assistance under a PAP became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary’s TrOOP or total Part D spending for any purpose. For the reasons noted in connection with pharmaceutical manufacturer PAPs discussed above, a PAP that provide assistance outside the Part D benefit only during the coverage gap (i.e., “wrapping around” the Part D benefit) poses a heightened risk of abuse. However, while it is difficult to assess the application of the fraud and abuse laws to PAPs that operate outside Part D absent a specific set of facts, it would appear that PAPs that furnish free outpatient prescription drugs entirely outside the Part D benefit pose a reduced risk under the anti-kickback statute, provided that:

(i) The PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by any Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary’s TrOOP;

(ii) The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance);

(iii) The PAP assistance remains available even if the beneficiary’s use of the subsidized drug is periodic during the coverage year;

(iv) The PAP maintains accurate and contemporaneous records of the circumstances, including the intent of the parties. We note that it would be important for the PAP program to cover additional products or manufacturers as they become available.

21 We are aware of nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers’ products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under his or her Part D plan. It is premature to offer definitive guidance on these evolving programs. Although these programs would operate so that the manufacturers effectively underwrite only the discounts on their own products, we observe that the risk of an illegal inducement potentially may be reduced if: (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy and a beneficiary’s choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for all of its products that are covered by any Part D plan formulary. Other safeguards may also be needed to reduce the risk of an improper inducement. Moreover, a program under which Part D enrollees pay a portion of their drug costs out-of-pocket would tend to reduce the risk of abuse by preserving the beneficiary’s incentive to locate and purchase equally effective, lower cost drugs.
IV. Bulk Replacement Models

Bulk replacement” or similar programs, pursuant to which pharmaceutical manufacturers (or their affiliated PAPs) provide in-kind donations in the form of free drugs to pharmacies, health centers, clinics, and other entities that dispense drugs to qualifying uninsured patients, are different from traditional PAPs that provide assistance directly to patients. These programs potentially implicate the Federal anti-kickback statute if the free drugs are given to a recipient that is in a position to generate Federal health care program business for the donor manufacturer. Whether a particular bulk replacement program complies with the fraud and abuse laws would require a case-by-case analysis. In undertaking any analysis, we would consider, among other factors, how the program is structured and whether there are safeguards in place: (i) To protect Federal health care program beneficiaries from being steered to particular drugs based on the financial interests of their health care providers or suppliers; (ii) to protect the Federal health care programs from increased program costs; and (iii) to ensure that bulk replacement drugs are not improperly charged to Federal health care programs. Additionally, bulk replacement as a means of subsidizing only the Medicare Part D cost-sharing amount potentially raises substantial risks related to accounting for the amount of replacement drug that would be equivalent to the cost-sharing amount owed by the beneficiary; properly attributing that amount to specific beneficiaries; and properly calculating TroOP.

V. Transitioning From Existing Pharmaceutical Manufacturer PAPs

OIG is mindful of the importance of a smooth, effective transition for beneficiaries who are currently participating in pharmaceutical manufacturer PAPs and elect to enroll in Medicare Part D. While most such enrollees are likely to qualify for the low-income subsidies available under Part D, we are concerned that there may not be sufficient independent charity PAPs available before the January 1, 2006 start date of the Part D program to accommodate beneficiaries of limited means who may need an alternative PAP arrangement. We recognize the importance of not unnecessarily burdening already-burdened beneficiaries. We believe that manufacturers will play an important role in ensuring an effective transition.

With respect to pharmaceutical manufacturer PAPs that are in existence prior to the date of publication of this Special Advisory Bulletin, during the initial calendar year of the Part D benefit, OIG will take into consideration in exercising its enforcement discretion with respect to administrative sanctions arising under the anti-kickback statute whether the PAP is taking prompt, reasonable, verifiable, and meaningful steps to transition patients who enroll in Part D to alternative assistance models, such as independent charities.

In addition to taking steps to transition beneficiaries to other programs, pharmaceutical manufacturer PAPs can reduce their fraud and abuse exposure by taking one or more of the following steps: (i) Adjusting financial need criteria to reflect the lower drug costs incurred by Part D enrollees (i.e., liability for premiums and cost-sharing amounts only, instead of the total cost of the drugs); (ii) where possible, subsidizing other drugs in the same class as the manufacturer’s products covered by the PAP if a beneficiary’s physician prescribes an alternate product; and (iii) checking CMS eligibility files, to the extent available, on a reasonably regular basis to determine whether PAP patients have enrolled in Part D and should be transitioned to other assistance programs. Occasional, inadvertent cost-sharing subsidies provided to a Part D enrollee should not be problematic (e.g., where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D). Notwithstanding a pharmaceutical manufacturer’s compliance with the foregoing, the Government will take enforcement action in cases where there is evidence of unlawful intent.

The potential variability of PAPs, the fact that the Part D program is not yet operational, and the fact that it is not possible to predict all future or potential fraud and abuse schemes with certainty, make it difficult to provide comprehensive general guidance on the application of the anti-kickback statute to PAPs for Part D enrollees at this time. We intend to monitor the situation closely and may issue further guidance, if needed. Nothing in this Bulletin should be construed as precluding any form of lawful assistance not described in this Bulletin.

VI. OIG Advisory Opinion Process

OIG has an advisory opinion process that is available to individuals and entities, including pharmaceutical manufacturers, that want assurance that they will not run afoul of the fraud and abuse laws. OIG advisory opinions are written opinions that are legally binding on OIG, the Department, and the party that requests the opinion. To obtain an opinion, the requesting party must submit a detailed, written description of its existing or proposed business arrangement. The length of time that it takes for OIG to issue an opinion varies depending on the complexity of the arrangement, including the complexity of the submission, and how promptly the requestor responds to requests for additional information. Further information about the process, including frequently asked questions, can be found on the OIG Web page at http://oig.hhs.gov/fraud/advisoryopinions.html.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the Department’s programs and to promote efficiency and economy in departmental operations. OIG carries out this mission through a nationwide program of audits, investigations, and inspections. The Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

Daniel R. Levinson,
Inspector General.

[FR Doc. 05–23038 Filed 11–21–05; 8:45 am]
BILLING CODE 4150–04–P

DEPARTMENT OF HOMELAND SECURITY
[DHSA2005–0054]
Office of State and Local Government Coordination and Preparedness; SAFER Grant Program

AGENCY: Office of State and Local Government Coordination and Preparedness, DHS.

ACTION: Notice and request for comment.

SUMMARY: Pursuant to the Paperwork Reduction Act, the Department of Homeland Security (DHS) solicited comments on the proposed collection of information in connection with the Staffing for Adequate Fire and Emergency (SAFER) Grant Application.

22 Section 1128D(b) of the Act; 42 CFR part 1008.
The decision to keep a patient assistance program is up to the pharmaceutical company, not the US government. The terms of the programs are determined by the company, without any government involvement.

There is nothing in the law that prohibits a pharmaceutical company patient assistance program from providing drug assistance to Medicare beneficiaries, even those enrolled in a Medicare prescription drug plan, but that help has to be outside the Medicare coverage—just as it has been until now.

No company needs to end its patient assistance program on account of the drug benefit starting. Lawful avenues exist for pharmaceutical companies and others to help Part D beneficiaries with their drug costs. Pharmaceutical company patient assistance programs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit. In these circumstances, the beneficiary obtains the patient assistance program drugs without using his or her Part D insurance benefit.

Specifically, pharmaceutical company patient assistance programs can provide coverage for particular drugs that are included in the Medicare drug benefit. This assistance would remain independent of the Medicare drug coverage, as it was before 2006. Any assistance a pharmaceutical patient assistance program provides to a Part D enrollee for prescription drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee’s true out-of-pocket costs (known as “TrOOP”) balance or total drug expenditures. In other words, beginning when a beneficiary’s assistance under a patient assistance program became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary’s TrOOP or total Part D spending for any purpose.

In fact, a company can continue its patient assistance program at a much lower cost than in the past, because most of the seniors eligible for pharmaceutical company patient assistance programs now have access to very comprehensive coverage through the Medicare program’s Limited Income Subsidy.

Nothing in any Office of the Inspector General (OIG) laws, regulations, or guidance prevents pharmaceutical company patient assistance programs from providing free or reduced price outpatient prescription drugs to uninsured patients and Medicare beneficiaries who have not enrolled in Part D.
• In addition, as outlined more fully in the OIG guidance, lawful avenues exist for pharmaceutical company patient assistance programs to assist financially needy Part D enrollees. The OIG has issued a Special Advisory Bulletin addressing the application of the fraud and abuse laws to pharmaceutical company patient assistance programs (see http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPerformanceBilletinFinal-Final.pdf).

  o The Bulletin explains that pharmaceutical companies face a heightened risk of liability under the fraud and abuse laws if they assist Part D enrollees by paying all or a portion of the Part D cost-sharing amounts owed by the Part D enrollees for the company’s products. For reasons explained more fully in the OIG’s Bulletin, these types of cost-sharing subsidies pose all the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries’ incentives to locate and use less expensive, equally effective drugs.

  o The Bulletin also makes clear that pharmaceutical companies may choose to provide free or reduced price drugs to financially needy Part D beneficiaries, so long as the assistance program is properly structured and the free or reduced price drugs are provided entirely outside the Part D benefit. They may also choose to make cash donations to bona fide, independent charities that assist Medicare beneficiaries with drug expenses.

• For example, suppose Ms. Smith has qualified for a patient assistance program for a particular, costly cancer drug. She signs up for Part D for her other medications, but her income and assets are too high to qualify for the Part D low-income subsidy. The pharmaceutical company could continue to provide her cancer drug through their patient assistance program, so that Ms. Smith continues to face the same out-of-pocket costs for the cancer drug as she did before. Ms. Smith would not get coverage from her Part D plan for the cancer drug. Because the pharmaceutical company would only need to provide such coverage for Medicare beneficiaries with incomes that are limited but too high to qualify for the low-income subsidy, the company could continue the assistance program for people like Ms. Smith at a significantly lower cost than before Part D began.

• If a company chooses to do so, it can have a “win-win”: significantly lowering the cost of its patient assistance program compared to before the drug benefit, so that it can help more people getting drugs they need, and at the same time they can make sure that all people who have depended on the pharmaceutical company’s patient assistance program in the past can get the same or more help.

• OIG guidance states that companies may enter into data sharing agreements with CMS to facilitate plan tracking of beneficiary drug utilization. CMS will work with companies interested in pursuing a data sharing agreement in accordance to the OIG guidance.
October 4, 2006

Memorandum To: All Part D Sponsors

Subject: HPMS Q & A - Patient Assistance Programs

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

The following question and answer on patient assistance programs operating outside the Part D benefit has been revised and updated in the Frequently Asked Questions Database on the CMS website at http://questions.cms.hhs.gov.

Q: Can patient assistance programs (PAPs) provide assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP?

A: We have previously advised that drug payments made by PAPs on behalf of Part D enrollees could count toward TrOOP, unless these organizations qualify as group health plans, insurance or otherwise, or other similar third-party payment arrangements. However, we clarify that we will allow PAPs the option of providing assistance for covered Part D drugs on behalf of Part D enrollees outside the Part D benefit. Under this option, a PAP would operate outside of the Part D benefit, and any assistance it provides to a Part D enrollee for drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee’s TrOOP balance or total drug spend. In other words, when operating outside the Part D benefit (and beginning at the point at which a beneficiary’s assistance under a PAP is effective), a claim for the drug for which a PAP had provided assistance would never be submitted to a beneficiary’s Part D plan.

Operating outside the Part D benefit does not preclude a PAP sponsor from requiring its enrollees – including those enrolled in a Part D plan – from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. We believe that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug overutilization, the assessment of anything but nominal cost-sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for those covered Part D drugs outside the benefit may never count toward enrollees’ TrOOP or total drug spend balances, we clarify that any nominal
PAP copayment amounts paid by Part D enrollees will be aggregated to their TrOOP and total drug spend balances, provided the enrollees take responsibility for submitting the appropriate documentation to their plan. It will not be permissible, however, for beneficiary payments structured as administrative fees or premiums to be aggregated to Part D TrOOP and total drug spend balances, as these types of beneficiary out-of-pocket expenditures do not meet the definition of “incurred costs” at 42 CFR 423.100.

Enrollee submission of this documentation is necessary because a PAP operating outside the Part D benefit should never submit a claim for assistance provided for a covered Part D drug to a Part D enrollee’s Part D plan. Consistent with our guidance on claims processing, plans should process these enrollee-submitted claims in the order in which they are received, not based on date of service.

As noted elsewhere, in order to facilitate implementation of this policy, plans should establish processes and clear instructions for enrollee paper claim submissions such that they can distinguish between claims submitted for: (1) out-of-network coverage; (2) adjustment to TrOOP balances based on wraparound payments by supplemental payers not previously submitted to the plan; (3) documentation submitted for a purchase made via a discount card or other special cash discount outside the Part D benefit in any applicable deductible or coverage gap phase of the benefit; and (4) documentation submitted for a copayment assessed by a PAP sponsor operating outside the Part D benefit for assistance provided with covered Part D drug costs. We plan to develop and share with plans model paper claims submission forms they can use or revise for these purposes.

The choice of whether to operate inside or outside the Part D benefit would be entirely at each individual PAP’s discretion, although the PAP would still need to comply with the Federal fraud and abuse statutes. We note that the issue of establishing criteria for applicability of PAP assistance remains up to each individual PAP. PAPs have discretion to decide at what point financial burden triggers PAP assistance – for example, a set income level or an asset test or a ratio of drug cost to income or assets. [We note, however, that a criterion of being uninsured would be problematic because we do not consider a Part D enrollee in the benefit’s coverage gap to be “uninsured” for purposes of a PAP’s determination of financial need. Although a Part D enrollee may be required to pay 100 percent cost-sharing until he or she has accrued $3,600 in TrOOP expenditures, that individual continues to have coverage under the Part D plan given his or her access to negotiated prices and continued payment of premiums.]

Once a beneficiary satisfies a PAP’s eligibility criteria, however, we believe the PAP should provide assistance through the end of the year. If, for budgetary reasons, a PAP declines to commit to providing assistance through the year, the PAP may decide to limit the amount of drug it will provide to any PAP enrollee. If a PAP decides to set such a cap, such cap should apply uniformly to all PAP enrollees - and not just to Medicare beneficiaries - and should be determined in a manner that is not directly or indirectly related to other drug expenditures by Part D enrollees. PAPs must not employ a cap to terminate PAP assistance in a manner designed to correlate with when the beneficiary's other drug expenditures might suffice to trigger catastrophic coverage under Part D or otherwise as a proxy for when Federal reimbursement would be available for the beneficiary's drugs. (Please refer to Appendix A...
for some examples of how TrOOP and total Part D drug spend are affected depending on when enrollment in a capped program takes place and whether an enrollee surpasses the cap in a given coverage year).

The option of operating outside the Part D benefit, with or without the assessment of nominal enrollee copayments for assistance provided, will allow PAP sponsors to continue providing needed assistance to financially needy beneficiaries – those whose incomes are too high to qualify for the low-income subsidy, but whose incomes are low enough that out-of-pocket costs on drugs are still burdensome – while allowing the individual PAPs flexibility to determine the form of their donations and, if operated with sufficient safeguards, to use existing PAP programs to assist needy beneficiaries. We note, however, that we will be monitoring the impact of this guidance and reserve the right to revise it for future plan contract years.

We also emphasize that the most effective – and, ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit would involve front-end data exchanges with CMS through the use of PAP-specific trading partner agreements, which we will provide further information about in forthcoming guidance. General information about eligibility file exchange with supplemental payers and other entities is provided in our coordination of benefits guidance. To the extent that a PAP exchanges eligibility files with us, we will be able to flag it as a non-TrOOP eligible payer for the particular Part D drugs it provides Part D enrollees at no cost. This information would therefore be available to plans through the TrOOP facilitation process, and plans would be alerted to the fact that they must follow up with the PAP to identify the prescription drug provided outside the benefit. This, in turn, would allow plans to set their systems to recognize that drug as part of a patient’s profile, while setting systems edits to prevent any payment for that prescription. As a result, a beneficiary will be able to obtain free product through the PAP without affecting either TrOOP or total drug spend amounts on plan PDE records. As a result of the data exchange process, the PAP will also receive information regarding its enrollees’ Part D enrollment status.

To address safety concerns associated with prescription drugs provided outside the Part D benefits, the front-end data exchange process will enable, as described above, plans to follow-up with PAPs to identify those Part D drugs an enrollee is receiving outside the Part D benefit. This will facilitate plans’ provision of required drug utilization review and, if applicable, medication therapy management program activities. If a PAP did not exchange information with CMS in the manner outlined above, such information would remain unknown to the plan, which could potentially lead to quality of care issues. For these reasons, we strongly encourage PAPs wishing to operate outside the Part D benefit participate in this process. Alternatively, a PAP could provide its enrollees with a notice they could provide to their Part D plans indicating that they are receiving one or more drug products from that PAP.

PAP sponsors, whether operating inside or outside the Part D benefit, remain responsible for complying with relevant fraud and abuse laws, including the anti-kickback statute. Liability under the anti-kickback statute requires a case-by-case analysis of the particular facts and circumstances, including the intent of the parties. However, to the extent that PAPs choose to operate within the Part D benefit, generally, the least problematic way of providing
assistance with the costs of covered Part D drugs to Part D enrollees is through support of independent PAPs operated by bona fide public charities without regard to donor interests. Properly structured, these programs can offer an alternative that reduces the risk of fraud or abuse. Among other things, the charity must make an independent determination of patient need, and the patient’s receipt of assistance may not depend directly or indirectly on the patient’s use of any particular product or supplier of drugs.

We have also received inquiries about the ability of PAPs to pay Part D premiums on behalf of enrollees or to provide free or discounted product through a coalition of manufacturers. Nothing in CMS rules and regulations prohibit such arrangements. We also note that organizations or entities offering patient assistance programs must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

**Examples of Impact on TrOOP and Total Part D Drug Expenditures in Capped Patient Assistance Programs**

**Scenario 1:** Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning January 1, 2007. Mrs. Jones uses $2,500 worth of free Drug ABC in 2007.

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<thead>
<tr>
<th>Donated Product</th>
<th>Dollar Value of Donated Product</th>
<th>Dollar Value of Donated Product Utilized</th>
<th>Impact on Total Drug Spend</th>
<th>Impact on TrOOP</th>
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<tr>
<td>ABC</td>
<td>$5000</td>
<td>$2500</td>
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**Scenario 2:** Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007.

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<th>Donated Product</th>
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<tr>
<td>ABC</td>
<td>$5000</td>
<td>$2500</td>
<td>$1265</td>
<td>$515 ($265 deductible plus 25% coinsurance on $1000)</td>
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**Scenario 3:** Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP Y. PAP Y imposes nominal cost-sharing of $5 for each prescription filled, and finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part D drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007. PAP Y imposes $50 of nominal beneficiary cost-sharing ($5 for each of 10 fills) between March 1 and December 31, 2007. Mrs. Jones submits the appropriate documentation to her PDP for all the nominal copayments assessed by the plan so that they may be aggregated to her TrOOP and total drug spend balances.

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<tr>
<td>ABC</td>
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<td>$2500</td>
<td>$1315 ($1265 of total drug spend prior to March 1, 2007, plus $50 in nominal PAP copayments)</td>
<td>$565 ($265 deductible, plus 25% coinsurance on $1000, plus $50 in nominal PAP copayments)</td>
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**Scenario 4:** Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning May 15, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and May 15, 2007, and she purchases no additional covered Part D drugs. She then uses $5,000 worth of free Drug ABC between May 15 and November 1, 2007. Since she has reached PAP X’s spending cap for Drug ABC, she begins to use her Part D benefit again for Drug ABC beginning November 1, 2007. She purchases $1,000 worth of Drug ABC between November 1 and December 31, 2007 (during this time period, she is in the coverage gap of the standard defined benefit given use of other covered Part D drugs throughout the year).

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<th>Donated Product</th>
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<th>Dollar Value of Donated Product Utilized</th>
<th>Impact on Total Drug Spend</th>
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<td>$1515 ($265 deductible)</td>
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<td></td>
<td></td>
<td>plus 25% coinsurance on 1st $1000 plus $1000 in coverage gap</td>
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Please contact Alissa DeBoy at (410) 786-6041 if you have any questions about this guidance.