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September 2010

Letter from the Editor: The "Mega Fine" Goes Giga: The Significance of Proactive Compliance Measures in the Age of Billion Dollar Penalties

by Jamie Ghen, Esq., CIS Director of Compliance, Ethics & Legal Affairs

17 to 1. This is not a reference to the odds of betting on a poker, basketball or football game, or even a horserace. 17 to 1 represents the return on the Office of Inspector General's (OIG) health care oversight investment reported as of 2009. Penalties for non-compliance have clearly increased over the past few years as "Medicare and Medicaid fraud, waste and abuse cost the taxpayers billions of dollars each year and put the programs' beneficiaries' health and welfare at risk." The growing number of people served by these programs, coupled with the increased strain on Federal and State budgets brought on by the economic recession, further exacerbates the impact of these losses causing penalties for non-compliance to rise into the billions practically overnight.

Normally, in the corporate context, talk about millions of dollars turning into billions of dollars is cause for celebration. However, pharmaceutical companies are not doing much celebrating these days. Civil and criminal penalties levied against them in the past decade or two have sky-rocketed, costing companies billions. It therefore comes as no surprise that pharmaceutical companies are taking great measures to establish, strengthen, and proactively assess their compliance programs. The days of pharmaceutical companies kicking compliance efforts into high gear after withstanding severe civil and criminal penalties for non-compliance with state and federal healthcare laws and regulations are gone. For example, over the last two decades, civil fines levied for off-label marketing of various drugs have skyrocketed from $5 million in 1995 to $2.3 billion in 2009. Pharmaceutical companies penalized for alleged off-label marketing practices include Ortho-McNeil® Pharmaceutical, Inc. ($5 million, 1995), Genentech Inc. ($50 million, 1999) , Elan Pharmaceuticals ($203.5 million, 2010), Cephalon, Inc. ($425 million, 2008), Eli Lilly ($1.42 billion, 2007) and Pfizer Inc. ($2.3 billion, 2009).

Notably, the massive scale of fines levied for non-compliance extend far-beyond the confines of the health care industry and involve companies such as Air France – KLM ($350 million, 2008, conspiracy to fix prices), LG Displays ($400 million, 2008, conspiracy to fix prices), BAE Systems ($400 million, 2010, non-compliance with anti-corruption practices), Halliburton/ KBR ($402 million, 2009, bribery of officials) and Siemens ($450 million, 2008, records falsification).

Along with the dramatic increase in non-compliance penalties over the past few years, there are no signs that the investigations and subsequent penalties stemming from the OIG's health care

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In This Issue

investigative oversight will slow down. Indeed, investigations for penalties for non-compliance undoubtedly will continue to rise with amendments to the Federal Sentencing Guidelines set to become effective November 1, 2010. In the pharmaceutical industry, fines levied harm employees, damage company goodwill, weaken relationships with doctors, and taint shareholder interests. Levied fines also lead large institutional buyers, such as the Department of Veterans' Affairs (VA), toward enacting more stringent policies which ultimately harm revenues. Proposed VA rule changes include: (a) the approval by the VA's Chief of Pharmacy of all "educational programs" implemented by pharmaceutical companies; (b) requiring appointments to visit VA facilities; (c) forbidding the distribution of food or gifts above negligible amounts; and (d) barring the distribution of drug samples at VA facilities. Non-compliance will result in, among other things, the suspension of sales representative access to the facilities, or in particularly egregious cases the denial of access privileges to a company's entire sales force.

The implementations of these fines are meant to encourage pharmaceutical companies to enhance compliance programs and internally eliminate non-conforming activities. Often, however, these penalties do nothing more than dent the multibillion-dollar revenues brought in by the drugs at issue while the company remains profitable. Consequently, the incentive for strong compliance may be mitigated if the implementation of a program cuts too heavily into profits. For example, while Eli Lilly paid $1.42 billion in 2007 for off-label marketing of its antipsychotic drug Zyprexa®, this amount was far less than the $9.45 billion in revenues the drug made in the years 2007-2008. Pfizer, which recorded its fine as a single quarterly liability, still managed to secure profits of $268 million. Spread out over the course of many years, that impressive fine becomes far more manageable upon the ledger.

Nevertheless, the heavy fines assessed so far have effectively spurred greater efforts toward compliance. For example, Pfizer began its corrective action before the announcement of its off-label marketing fine. Pfizer implemented a Corporate Integrity Agreement (CIA) that "[went] further" than that of Eli Lilly and Cephalon. Pfizer's CIA places more accountability on individual employees with the hope that it will steer sales representatives away from unethical or illegal practices. Not only does the placement of accountability on individual employees correspond with proposed amendments to the Federal Sentencing Guidelines, this focus on personal responsibility decreases a sales representative's inclination to perform through unethical or illegal behavior.

Recognizing Pfizer's focus on downstream marketing to thwart unethical or illegal sales representative behavior, Ethisphere™, a think tank "dedicated to the creation, advancement and sharing of best practices in business ethics, corporate social responsibility, anti-corruption and sustainability," took a look at Pfizer's efforts as "One to Watch" in their annual ranking of the "World's Most Ethical Companies." Ethisphere™ noted that Pfizer developed a risk mitigation program (RAMP) and increased its internal auditing efforts, including scanning for potential violations of the Foreign Corrupt Practices Act (FCPA) in internal audits. As some of the above-listed penalties were in response to FCPA violations, this sort of auditing may be critical toward establishing an effective global compliance regimen, since it is much more difficult when a company cannot rely on national norms in its home territory.

While the loss of $2.3 billion is dramatic to most, Pfizer is a company large enough to withstand receiving such a penalty. Eli Lilly, fined $1.4 billion for the same off-label marketing violations, falls within this same category. On the other hand, smaller companies are without resources to sustain such a penalty. While current penalties seem to scale with the amount of sales associated with a pharmaceutical company, this cannot be assured for the future, particularly if the harm inflicted by the company is far-reaching and profound. Greater, proactive compliance due diligence is therefore required for small companies to off-set potential penalties.

Proactive compliance requires a lot of time, money and resources. For larger companies, costs and resources associated with proactive compliance measures do not seem to be as problematic as they are for those companies smaller in size. For example, IBM's European Life Sciences and Pharmaceutical division compliance measures account for around 25% of each plant's operating costs. In their estimation, the only means of reducing these costs is by abandoning a "cause no problems" approach; that is, relaxing on efforts toward full compliance. The model suggested is a risk management approach, balancing the costs of full compliance with the risk of punishment for failure to comply. The interesting thing, however, is that among best in class companies, as efforts toward compliance increase, the cost of compliance decreases.

As the industry continues to watch the compliance mega-fine spiral beyond the Giga, the risks associated with not proactively implementing and monitoring a comprehensive global compliance program will far outweigh any short-term reward.

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The CIS compliance experts speak at a variety of industry events and are often available to discuss current issues affecting government programs professionals. Be sure to stop by our booth to meet them!

Should You Sign the CMS Part D Discount Agreement If You Do Not Have Part D Covered Drugs?

An Update on Part D Plan Agreements From Conversations with Marla Rothouse at CMS

by Chris Cobourn, CIS Vice President, Regulatory Compliance

The due date for manufacturers to sign the Medicare Part D Discount Program Agreement and the TPA agreement has passed.

If manufacturers did not sign the agreement, their drugs will not be covered by Medicare Part D at all (i.e., before, within and after the coverage gap) in 2011, and they will have to sign the agreement by January 30, 2011 to participate for the 2012 benefit year.

Many of our clients do not participate in the Medicare Part D Plans, as they have more "inpatient" or ASP types of drugs. Additionally, it seems that many of our clients are unsure whether they should or should not sign the agreement with CMS, and what the impact will be based on their decision.

In a recent conversation with Marla Rothouse, acting Director for the Division of Pharmaceutical Manufacturer Management at the Centers for Medicare & Medicaid Services (CMS), Marla and I walked through several scenarios, providing me assistance with the language that CIS could put out on the blog. (Also, I will be adding another blog this week with an update on the specifics of the Model Agreement and the other recent updates by CMS).

Background reading:
In an August 3rd Memo, CMS states that they "encourage" all manufacturers to participate, regardless of whether the manufacturer's drugs are currently "covered," covered meaning that they are a Part D Drug on a plan formulary:

> *CMS encourages all manufacturers, including all labelers, relabelers, repackagers and distributors with their own FDA assigned labeler codes, of prescription drugs products that are covered under Part D to sign the agreement even if your company does not believe any of its products are applicable drugs. If it turns out that your company does not have any applicable drugs, signing the Agreement does not impose any discount requirements. However, if you fail to sign the Agreement and later determine that some of your products are indeed applicable drugs, your company will not have another opportunity to sign an Agreement for 2011 and any such products cannot be covered under Part D until 2012 at the earliest.*

The following are several scenarios that Marla and I discussed to understand how the "non-covered drug" (not on a plan's formulary) could be impacted:

Scenario 1: Manufacturer signs the agreement with CMS, but is not on a plan formulary.

The beneficiary would have to acquire an exception from the plan, as the product is not on their formulary. If they receive an exception, the discount applies and the manufacturer *would* receive the invoice for the discount reimbursement.

If the beneficiary does not receive the exception, then the drug does not meet the definition for a covered Part D drug, the beneficiary would pay 100% during the coverage gap, and the manufacturer does not receive an invoice.

Scenario 2: Manufacturer does not sign the agreement with CMS, and is not on a plan formulary.

The drug would not be covered during the coverage gap, regardless of whether the beneficiary receives an exception from the plan. The beneficiary pays 100%. The only other option would be if CMS makes its own specific exception, and Marla indicated that they do not plan on making any exceptions.

Some of our clients have inpatient or ASP type of drugs that are "covered" under Medicaid as Medicaid as a blanket agreement.

We do see some a small number of Medicaid claims that fall into the "brown bag" scenario, where a patient gets a prescription, fills it in a retail setting, and brings it back to the doctor's office. I think this "brown bag" scenario is also where we may see some Part D purchases during the coverage gap for the non-Part D drugs. So, according to Marla, if you do have the agreement in place with CMS, these purchases would be "covered" under the program even though your product is not a covered product.

On a closing note, Marla reinforced that CMS encourages participation, to ensure that in the event of Scenario 1 above, the drug is covered and the patient does not have to pay the full cost of the drug. She also adds that "Part D is not just a retail setting program; it is also applicable in other settings, such as long-term care." Marla suggests that all manufacturers should consider participating, just in case there are eligible covered purchases.

Part D Discount Program Update, CMS Issues Final Model Agreement: Time to Prepare for 2011

by Chris Cobourn, CIS Vice President, Regulatory Compliance

As you may be aware, CMS recently updated its Part D Discount Program guidance, posting several documents on its website.

These documents include:

- The Model Agreement
- The Third-Party Administrator Agreement
- A Memo from CMS on the Manufacturer Agreement (This is very interesting, as it provides responses to comments from the comment period. See below.)
- The Contact Information Submission Instructions.

What happens if you didn't sign up by the Sept. 1st deadline? Below are a few follow-up points that you should be aware of on the updated guidance.

If manufacturers have a drug that is not a covered Part D Drug, and are wondering if manufacturers should sign the agreement, I encourage all to read my blog posting on this, which summarizes my conversation with Marla Rothouse from CMS.

August 3rd CMS Memo

This reiterates the date of September 1 that CMS is looking to receive the signed agreements.

It also summarizes the responses to manufacturers' comments on the draft agreement, the TPA agreement, and the data use agreement.

Comments and responses on the Draft Agreement (see my previous blog article concerning the draft agreement):

- The 14-day period for processing the claims;
  CMS has revised the timeframe to 38 days.

- The requirement that manufacturers pay invoices even when amounts are in dispute;
  CMS has not changed the original requirement, meaning that manufacturers must pay on the invoice and dispute afterwards. CMS comments, "CMS will be performing extensive editing on the data prior to invoicing manufacturers," suggesting that they believe that the quality of the PDE data will be high.

- The level of detail for the information that would be provided to the manufacturers to support the discount payments;
  CMS revised the level of data that will be provided to manufacturers along with the invoice to be claim-level utilization information and, in addition will upon audit only, provide PDE cost elements for a statistically significant sample size to allow manufacturers to validate discount calculations. CMS will not provide any beneficiary identifiable information, even upon audit

Comments and Responses on the TPA and Data Use Agreements

- The data use requirement that manufacturers meet federal data security standards that are required for federal government agencies — manufacturers raised concerns that this requirement was overly burdensome and would require them to overhaul their existing security programs solely for participation in the CGDP (Note – I discussed this concern, as mentioned in a recent blog article).
  CMS revised this specific requirement because CMS will not be releasing PHI to manufacturers. The agreement maintains requirements for manufacturers to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to it.

- The data use requirement that manufacturers are not to sell, rent, lease, loan, or otherwise grant access to the data covered by the agreement— manufacturers asked CMS to clarify that manufacturers may grant access to data to contracted third parties for purposes of assisting the manufacturer in evaluating the accuracy of claims discounts, resolving disputes and otherwise exercising their rights and responsibilities under the agreement.
  CMS clarified in the revised agreement that such access is allowed (this is near and dear to CIS, as we process Medicaid and TRICARE claims for our clients, and have been asked to process the Part D Coverage Gap Discount Program Claims as well).

- The language in the TPA Agreement suggesting that manufacturers would be bound by the contractual arrangement between CMS and the TPA — manufacturers raised concerns that CMS is obligating them to comply with unknown provisions in CMS's agreement with the TPA.

  CMS clarified in the revised version that only the TPA is governed by the contractual arrangement between CMS and the TPA.

I do not see the update separate data use agreement. CMS did indicate in the memo that they responded to the manufacturer

comments and revised the data use agreement. I do see that in Exhibit C of the Model Agreement there is a Data Use Provisions section. This section does include the phrasing:

> *...the Manufacturer agrees 1) to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability Accountability Act; and 2) to use the prescription or claim-level data only for purposes of evaluating the accuracy of claimed discounts and resolving disputes concerning the Manufacturer's payment obligations under the Discount Program as described in the applicable statutes, regulations, and this Agreement.*

This is followed by specific requirements, including areas where manufacturers had concerns about the draft Data Use Agreement:

> *In the event that a Manufacturer inadvertently receives individually identifiable information, the Manufacturer will report the incident to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the incident.*

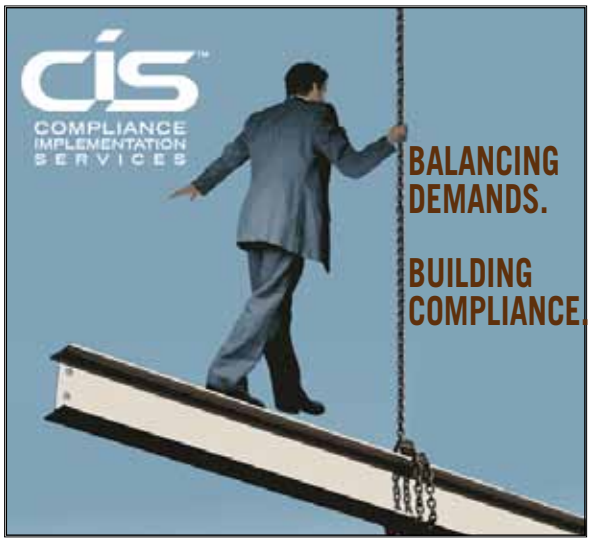
> *The Manufacturer hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106.*

It is very important that as manufacturers look at implementing the Part D Discount Program that they coordinate with Legal and IT to ensure that there are very tight security controls on the receipt, use and access of the data so that manufacturers can meet these security requirements.

Also on page 4 of the CMS Memo, CMS "encourages" manufacturers to participate (it was another open question on whether manufacturers were required to participate):

> *CMS encourages all manufacturers, including all labelers, relabelers, repackagers and distributors with their own FDA assigned labeler codes, of prescription drugs products that are covered under Part D to sign the agreement even if your company does not believe any of its products are applicable drugs. If it turns out that your company does not have any applicable drugs, signing the Agreement does not impose any discount requirements. However, if you fail to sign the Agreement and later determine that some of your products are indeed applicable drugs, your company will not have another opportunity to sign an Agreement for 2011 and any such products cannot be covered under Part D until 2012 at the earliest.*

As stated earlier, please see my article summarizing my conversation with Marla Rothouse of CMS on how purchases within the coverage gap could be impacted if manufacturers do not have Part D drugs but do sign the agreement with CMS.



What Recourse Does Manufacturing Have to Audit a 340B Entity?

by Lauren Pellicciotti, CIS Government Pricing Project Manager, and Chris Cobourn, CIS Vice President of Regulatory Compliance

For years, manufacturers have been wrestling with certain aspects of the Public Health Service ("PHS") program, such as areas related to disputing certain 340B purchases. There has been limited guidance, although the Office of Pharmacy Affairs ("OPA") has communicated certain expectations. Manufacturers have had limited visibility in to the actual transaction, and rely on chargeback data after the purchase. The manufacturer may identify chargeback activity that raises questions, but they are not certain what they can do, or what they should do. Key scenarios include:

- Cases where a hospital purchases under a GPO contract, a clinic that purchases under the PHS contract, and there are purchasing trends that suggest that the hospital is purchasing under the PHS contract for inpatient use.
- Additionally, instances where there is a drug that is primariy used in an inpatient setting (i.e. for a heart transplant) and there is activity at certain entities (which could be legitimate) with high levels of PHS purchasing.

In each of these cases, manufacturers often ask us what they should do, and if they are obligated to do anything. A critical first point to understand is that the manufacturer's accountabilities under the program are different from those of the entity. The manufacturer is expected to calculate and report the price, and to honor the price on chargebacks. The entity is expected to purchase for legitimate outpatient use by the eligible entity. It is not the manufacturer's responsibility to make sure that the entity is following the law. However, if the manufacturer identifies potential issues, I think that they have the right, and to some extent the responsibility (although there is no guidance in this area), to contact the entity and conduct research. I believe that to do this, the manufacturer has to have some data behind them. This can include trending and analysis on normal purchasing trends for a specific type of product, so that if they contact an entity, they can identify that there appears to be purchases outside the norm, and to ask for some evidence that these were legitimate purchases.

If a manufacturer conducts this analysis with an entity and the entity is unable to provide sufficient documentation, then the manufacturer has the right to make the OPA aware of the situation.

I believe that the OPA's position (again, there is no written guidance) is that a manufacturer should pay the chargeback and then conduct the analysis, that they cannot deny the chargeback up front. I know that some companies have sought additional legal opinions, and in some cases have adopted policies to deny certain chargeback activity.

Which brings us to the next point…

What if the entity is not forthcoming with transparency or data? Can the manufacturer conduct an audit? I believe they are able to do so, but I also believe that how cooperative an entity may be is questionable, and the OPA probably does not have resources or guidance to help enforce the right to audit.

Below, Lauren Pellicciotti, Government Pricing Project Manager, summarizes an Office of Inspector General ("OIG") audit of an entity.

For the period July 1, 2001 through December 31, 2002, the OIG performed an internal audit on a County Health Department on purchasing of pharmaceuticals under the 340B program (i.e., the PHS program). Below is a summary of findings from the OIG audit:

- "County Health Department did not exercise and ensure proper contract execution and Monitoring; and
- Pharmaceuticals purchased by the County Health Department under PHS account numbers were dispensed to clients outside of Covered Entities." [1]

This example demonstrates that there are instances in which covered entities are not following the rules of the 340B program. The good news is that the new requirement of the annual certification for the covered entities could solve a lot of manufacturers' concerns about the program. Manufacturers feel that they cannot properly verify a PHS purchase on their indirect contract outdated information. The entity may be ineligible.

What is the program really about?

> *The 340B Drug Pricing Program was established in response to the passage of Section 340B of U.S. Public Law 102-585, the Veterans Health Care Act of 1992. Section 340B of this law limits the cost of drugs to certain grantees of federal agencies and other entities identified in the statute. Significant savings on pharmaceuticals may be seen by those entities who participate in this program. The program is administered by the Office of Pharmacy Affairs ("OPA") of HRSA, under the federal Department of Health and Human Services (HHS). [2]*

According to the Pharmacy Affairs branch, covered entities must maintain accurate records documenting that the entities are not double dipping or reselling, or transferring drugs to persons who are not patients of the entity. It is required that all covered entities *must* present records in the case of an audit by the manufacturer or the federal government. An entity that fails to comply with these requirements will be liable, after notice and hearing, to the manufacturer in an amount equal to the reduction in price of the drug provided in the Section 340B agreement. [3]

Sources
[1] http://bit.ly/chqn0x
[2] http://bit.ly/9QXBjO
[3] Pharmacy Affairs Branch website http://www hrsa.gov/opa And Katheryne Richardson, Pharm.D.: http://pssc.aphanet.org/pdfs/340b_handbook.pdf

Will States Carve Prescription Drugs Back into Medicaid MCOs?

("To Carve or Not to Carve, That is The Question…")
by Kyle Hodgin, CIS Compliance Associate

When the Medicaid Drug Rebate Program (MDRP) was instituted in 1990, it required manufacturer rebates for prescription drugs dispensed to eligible Medicaid patients. However, it only required these rebates for drugs dispensed through retail pharmacies on a Fee-for-Service basis. This is significant because many Medicaid beneficiaries are now enrolled in Medicaid Managed Care Organizations (MMCOs) for their health care. Prescription drugs dispensed to a Medicaid patient by a Medicaid MCO were not eligible for the manufacturer rebates provided to states for drugs dispensed through the Fee-for-Service system. One of the significant changes that health care reform brings is the extension of manufacturer rebates for prescription drugs to include those dispensed by MMCOs to Medicaid patients.

It is possible that certain states will realize a cost savings as Medicaid rebates become available for the first time for this type of utilization. While MMCOs are able to negotiate commercial rebates, (estimated at 5% for branded drugs, 0% for generics), they are not as substantial as the rebates required for units dispensed to Medicaid patients under the Fee-for-Service system. These statutory rebates (now a minimum of 23.1% of AMP for branded drugs, 13% for generics) are now available to the states for units dispensed to Medicaid patients by MMCOs. However, some states may not realize a cost savings from the change due to the fact that they are already "carving out" the pharmacy benefit from services provided to Medicaid patients by MMCOs, thereby receiving the required rebates [1].

To "carve out" the pharmacy benefit simply means that the "drug benefit" is not part of the services provided to Medicaid patients by the MMCO under the capitated agreement with the state. To obtain rebates for all Medicaid drug utilization, some states established the drug benefit for all Medicaid patients as a Fee-for-Service arrangement, regardless of whether these patients received the remainder of their health care through an MMCO. While enrollees in Medicaid Managed Care receive the majority of their care from the MMCO, the prescription drug benefit is managed under Medicaid Fee-for-Service. This allows drugs dispensed to Medicaid patients through MMCOs to be eligible for the federal Medicaid rebate. The application of these rebates has led to a cost savings on prescription drugs for states that carved out the drug benefit from MMCO health care service contracts. However, there are other drivers that can offset, at least partially, the benefit of carving out prescription drugs:

- It is believed that MCOs can be more efficient when it comes to managing drug utilization. Because the organization coordinates care across physicians and conditions for a single patient, the MCO is able to achieve cost savings by managing the use of prescription medications. Medicaid Fee-for-Service is less able to coordinate data and information from physicians concerning a patient's condition in order to efficiently manage prescription drug use.

- MMCOs have a significantly higher generic fill rate than Medicaid Fee-for-Service. Because generics are generally less expensive compared to branded drugs, MMCOs can realize a deeper pre-rebate cost savings because they prescribe more generics than Medicaid Fee-for-Service.

- MMCOs not only prescribe a higher rate of generics, but can limit the formulary to a less expensive list of branded drugs, requiring the patient to either pay out of pocket for drugs not on formulary, or pay a higher proportion of the costs. While the MDRP requires states to provide access to all, the states may restrict the use of any product through a state Medicaid formulary. This is often determined by a supplemental rebate program which requires manufacturers to pay rebates in addition to the basic MDRP rebates [1].

These drivers in a worse-case scenario can potentially erase any cost savings realized by carving out the Medicaid MCO benefit to Medicaid Fee-for-Service. However, several states concluded that while the savings from the carve out were partially offset by the above drivers, the net financial impact was favorable.

One important question to consider is: If efficiencies realized by MMCOs are substantial enough to offset some of the positive effect of a carve out, will the carve out states consider adding the pharmacy benefit back into MMCOs in order to potentially realize an even greater cost savings than before?

Aside from owing additional rebates for prescription drugs dispensed to Medicaid patients by MMCOs, "carving in" could also have the following effects on manufacturers:

- Manufacturers with branded drugs could see a slight decrease overall in utilization.

- Manufacturers with higher-priced drugs in a given therapeutic class could see a decrease in Medicaid utilization.

- Generic manufacturers could see a slight increase in utilization due to the higher generic fill rate of MMCOs (This could potentially be offset by the higher rebate percentages required under HCR).

The idea of carving out or in definitely has implications given the addition of manufacturer rebates to MMCOs. The full impact on carve-in vs. carve-out states can only be seen after data begins to come in for utilization in MMCOs and manufacturers begin to pay the rebates. Until then, the only sure thing is that manufacturers will see an increase in rebates owed for Medicaid utilization in states that have not carved out.

Each state will have to perform extensive fiscal analysis to determine whether they will realize a net savings by maintaining a "carve out" of the drug benefit from health care services provided by MMCOs, or having MMCOs provide all services, including the drug benefit.

Sources
[1] http://bit.ly/dC0NZj
[2] http://bit.ly/bdLmt3

How Effective Is DTC Advertising, Really?

By Jess Ebert, CIS Compliance Associate

The pharmaceutical industry is taking a lot of heat these days in the Direct-to-Consumer (DTC) advertisement department. Companies have more options to effectively reach and market their products to consumers; starting with radio, television, and literature and more recently moving into social media tools and the Internet. The industry has seen a lot of guidance issued in the past year regarding how information is to be appropriately presented to consumers with a continued emphasis that the information provides a fair balance between the risks and benefits of a product. Recently, the FDA's Division of Drug Marketing, Advertising, and Communication (DDMAC) rolled out the "Bad Ad Program" to educate providers on how to spot and report misleading drug promotion (for more information on the Bad Ads Program, check out Kim Gilbert's article "FDA Rolls Out "Bad Ads Program"[1]). Through its efforts, the FDA makes clear that consumer perceptions regarding product safety is important, but my question is, how many people are really affected by all of these advertisements? Does anyone actually call up their doctor and request a medication just because they saw, heard and/or read an advertisement?

I thought about this the other day as I was perusing a magazine. I counted 11 drug advertisements. Yes, 11! While it can be slightly annoying to be bombarded with drug advertisements while reading a magazine, I understand that advertising in magazines creates awareness in consumers that a product exists that could possibly help with a condition. However, I could not help but wonder how other people feel about all of this drug promotion, and how many actually end up taking the drug that they saw the ad for in the first place.

Apparently, other people were asking this very same question.. Indeed, I found a few surveys conducted in the past several months regarding DTC advertising, and the results were very interesting. First, the Thomson Reuters PULSE Healthcare Survey collected information from more than 3,000 participants on their response to and attitudes toward promotional drug advertising. The participants were asked to respond to questions such as "did any of the advertisements influence you to ask your physician about a specific medication," "did your physician give you a prescription for the medication," and "what is your main source of information for prescription medications (options were doctor, pharmacist, internet, and other)." According to the survey:

- Roughly 65% of respondents confirmed that they had seen, heard, or received drug advertising, but **only 8% of that group actually was influenced to talk to their doctor about the specific medication.**
- Slightly more than 30% of the group that talked to their doctor about a medication actually received a prescription for what they requested.
- Almost 58% of respondents said they utilize their doctors as their main source for information regarding prescription medications, followed by "other" at 23.1%, internet at 11.2% (which was surprising to me, because the first thing I would do is research to exhaustion), and pharmacist at 7.9% [2].

The second survey I found was Prevention Magazine's 13th annual national survey Consumer Reaction to DTC Advertising of Prescription Drugs. The survey was based on roughly 1,500 participants and focused on several points, including how fair and balanced consumers perceive drug advertisements to be, how appropriate consumers thought ads were in the social media landscape, and how likely ads were to influence consumers to talk to their doctors about the specific medication. Here are a few highlights:

- 57% of consumers said that online DTC advertising was appropriate on websites that are related to health and medical issues.
- 33% of respondents said they had conversations with their doctor about a medication that they saw an ad for;
    - 19% asked for the medication after discussing the options with their doctor
    - 79% had the conversation, but didn't ask for the medication
- 61% of respondents asked for a generic or less expensive medication, indicating little to no brand loyalty [3].

It is interesting to see how consumers respond to drug promotion. Generally speaking, it seems that the majority of consumers that participated in both studies were exposed to some form of drug advertisement, and that a large percentage were influenced enough to seek additional information from their physician. While it seems like most of the people that request a specific medication do not actually end up receiving a prescription for it, there is also a lack of brand loyalty. Billions of dollars are spent every year on reaching out to consumers, but according to these surveys, it does not seem like much of a manufacturer pay off.

Sources

[1] http://www.pharmacomplianceblog.com/blog/?p=2140
[2] http://www.factsforhealthcare.com/pressroom/NPR_report_PrescriptionDrugs.pdf
[3] http://newsblaze.com/story/20100715090202000002.bw/topstory.html