Life & Health

Health Care Communiqué

Q3 2014

INVESTING IN YOUR COMPLIANCE PROGRAM

On June 24, 2014 CMS held a conference on the topic of Program Audits in 2014. A focus of the discussion was on a plan's investment into its Compliance Program. CMS invited plans of varying sizes to come and speak about their organization's compliance program and what they have implemented to ensure that the program they have in place is effective. There were several overarching themes that presented themselves throughout each speaker's presentation.

One of the themes that was evident throughout the presentations was the need to have appropriate structure in order to have a successful Compliance Program. Structure is needed within all aspects of the organization. It needs to begin within the corporate governing body

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INVESTING IN YOUR COMPLIANCE PROGRAM *(Continued)*

and the leaders of an organization must be actively engaged in order to demonstrate the importance of compliance. Developing appropriate structure should also include:

- Holding regularly scheduled meetings for Medicare leadership, frontline staff, specific operational areas, etc.
- Creating tools and processes that are customized based on area of operation
- Having tracking mechanisms in place, dashboards and regular updates that are distributed throughout the organization, etc.

Oversight of First Tier, Downstream and Related Entities (FDRs) was also a focus of discussion. This tends to be a challenging area for plans and they need to make sure that they have appropriate oversight of any delegated functions. FDRs (like a PBM) are an extension of the plan. Plans need to actively oversee any functions that are delegated. They need to conduct a review of processes that the FDR has in place to validate that they align with CMS regulations.

Communication was repeatedly highlighted as an important aspect of having an effective compliance program. CMS values when plans provide feedback to them. They utilize feedback from the plans in developing strategies and timelines when regulatory changes are introduced. In addition, other areas of communication that were highlighted during the call include:

- Creating open dialog within a plan's organization; establishing hotlines, protocols for reporting non-compliant issues, etc.
- Partnering with FDRs and having open communication as part of a plan's FDR oversight strategy
- Actively engaging with the CMS Account Manager with regular calls to discuss any open issues or questions

CMS promotes transparency. They expect plans to be proactive in the resolution of issues and to engage CMS. The goal is to help plans be compliant. They want to ensure that members are receiving the services that they are entitled to. The protocols that CMS has developed are based on desired outcomes that ultimately benefit the member. Having an effective Compliance Program in place that includes structure, FDR oversight and communication will lead to better outcomes.

HHS HIPAA SELF-ASSESSMENT TOOL AIDS WITH SECURITY RULE COMPLIANCE

HIPAA compliance is challenging due to the myriad requirements under different rules and sections of the legislation, as well as the number of areas of potential exposure. While the HIPAA Privacy Rule sets national standards relating to the use and disclosure of individuals' Protected Health Information (PHI), the HIPAA Security Rule specifies a series of administrative, physical and technical safeguards to assure the confidentiality, integrity and availability of electronic Protected Health Information (ePHI). The Security Rule is highly technical and compliance is challenging especially for smaller covered entities and business associates.

The Office of the National Coordinator for Health Information Technology (ONC), in collaboration with the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR), has released a Security Risk Assessment (SRA) Tool to assist entities in complying with the HIPAA Security Rule.

A component of the HIPAA Security Rule requires most covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of their ePHI. Potential financial penalty for required organizations who fail to make such an assessment and experience a breach can be costly.

Recent high profile cases include:

- A settlement in May 2014 when two health care organizations were responsible for paying $4.8 million to HHS, the largest HIPAA settlement to date, for violations of HIPAA Privacy and Security Rules. The covered entities failed to secure the ePHI of 6,800 patients held on their network by disclosing patient information on the internet. Additionally, the organizations had not conducted an accurate and thorough risk analysis of the systems which prevented them from developing and implementing appropriate policies and procedures for authorizing database access.
- In August 2013, a managed care health plan was responsible for paying over $1.2 million for violations of HIPAA Privacy and Security rules. The health plan had impermissibly disclosed the PHI of its members when it returned multiple photocopiers to a leasing agent without erasing the data on the copiers' hard drives. Further, they had failed to incorporate the ePHI stored in the copiers' hard drives in its analysis of risks and vulnerabilities as required by the Security Rule, and failed to implement policies and procedures when returning the hard drives to its leasing agents.

The SRA Tool is meant to assist covered entities and business associates as they perform and document HIPAA risk assessments. The SRA Tool is an independent application that can be downloaded from the HHS website (or downloaded in a paper-based version). The tool walks the user through each HIPAA requirement by presenting questions about the entity's activities. There are 156 questions relating to administrative, technical and physical safeguards, including security practices and failures, risk management and personnel issues, as well as a place for the user to add personalized comments. Resources are included for each question, such as definitions, explanations of potential risks and examples of safeguards. Finally, the SRA Tool is self-contained, meaning that the user can store the information on their computer for future reference or for generating reports.

The SRA Tool is not a required compliance item — it is simply meant to assist covered entities in complying with the HIPAA security rules. It does not cover any HIPAA privacy requirements, does not guarantee HIPAA compliance and does not replace the use of counsel for a customized assessment of PHI risks. However, it may be a useful resource for a basic risk analysis.

The SRA tool can be found at http://www.healthit.gov/providers-professionals/security-risk-assessment-tool

RISING COST OF PRESCRIPTION COMPOUNDS

The rising cost of compound prescription drugs is becoming an element of focus among health care payers.

According to one national prescription drug benefit manager (PBM), costs of compounded prescriptions have risen over the past two years, with observations of payers experiencing up to a 218% average increase in CY 2013 in year-over-year drug spending on compounded medications. The average per claim costs rose from $98 to $195. Reasons for this spike appear to be due to:

- Increased cost and AWP price increases of individual ingredients in compounded prescription claims.
- Changes in National Council for Prescription Drug Programs (NCPDP) claims submission standards for compounded prescriptions.
- Increased utilization of medications for indications that have not been fully studied.

In pharmacy compounding, a licensed pharmacist combines, mixes or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient. Compounded prescriptions (compounds) combine two or more drug ingredients to make products that are otherwise commercially unavailable. These products are tailored to fit individual needs, such as:

- Changing a solid into a liquid.
- Providing medication when there is a shortage of the traditional medicine (as seen recently with drugs that treat flu).
- Offering smaller doses than are provided in traditional medications.

Compounds are medically necessary in some cases. However, there is an increasing prevalence of compounds that are either not medically necessary or prescribed for conditions not approved by the Food and Drug Administration (FDA). Without the appropriate clinical programs or member contract language in place, we have seen health care payers incur costs up to millions per year for compound claims. This trend should concern payers because of not only unnecessary pharmacy costs, but because of safety issues, which include:

- Poor compounding practices that can result in contamination.
- Products that are not regulated by the FDA; therefore there is no testing for appropriate strength. This can potentially cause harm from patients taking either too little or too much of the medication.

There are also several financial concerns. Though most pharmacies have systems that identify compounds by each ingredient, less sophisticated systems may allow compounds to bypass certain checkpoints and cause the following:

- Double-billing – The pharmacy dispenses multiple fills for the same types of drugs.
- Bypassed drug utilization reviews – Disease-to-drug and drug-to-drug interactions are not caught prior to the point of sale.
- Therapeutic duplication – The same drug in different dosage forms reaches a member without being flagged.

RISING COST OF PRESCRIPTION COMPOUNDS *(Continued)*

The impact of the high-cost compounds can be mitigated by implementing appropriate clinical programs to ensure pharmacy claims meet standards for medical necessity.

- Payers should consider program strategies that implement an exclusion and non-coverage of any claim for a compound that includes bulk drug chemicals/powders. Executing this strategy largely rests on a rationale that the rejection of claims containing bulk drug chemicals/powders is not FDA approved and does not allow process for exceptions requests or appeals. Therefore, before considering this option, Solid Benefit Guidance, LLC (SBG) recommends to confirm member benefit contracts that allow a complete exclusion (without review for medical necessity or appeal). Generally, member benefit contract language addresses contract exclusion or non-coverage of prescriptions/claims containing non-FDA approved drug products.
- In cases where contract language cannot currently support contract exclusion of bulk containing compounds, SBG recommends applying prior authorization of top bulk drug chemicals for medical necessity review. This may vary by payer, but some of the top bulk drug chemical compounds of concern that have been observed to drive cost include: diclofenac, flurbiprofen, ketoprofen, gabapentin, ketamine, hyaluronic acid, mometasone, fluticasone, nabumetone and meloxicam.

While intended to address special pharmaceutical needs of individuals, compounds tend to be significantly more expensive than commercial formulations. In many cases, there are Food and Drug Administration-approved alternatives for compounded medications.

Other best practice approaches include:

- Close collaboration with provider networks to ensure they are aware of compounding concerns and have the clinical and evidence-based medicine guidelines needed to choose the optimal therapy.
- Ongoing prospective and retrospective claims review.
- Patient and prescriber education and support.

COPAXONE

(glatiramer acetate injection) 40mg – Formulary or Non-Formulary

In January 2014, Teva announced the FDA approval of a subcutaneous three times-a-week formulation of Copaxone 40mg/mL, as another option to its 20mg once-daily formulation. This came at a crucial time of the much-anticipated generic availability of Teva's daily Copaxone 20 mg/mL product that was set to become available in May 2014. This date has come and gone with the generic availability mainly dependent on FDA generic drug approvals and the capacity of the generic filer. Momenta Pharmaceuticals and its partner Sandoz are to launch their product when the approval is received. It is uncertain if Teva will be successful in staving off generics by persuading the FDA to require additional clinical studies for approval. Teva estimates about $78 million in sales for every month that Copaxone keeps its exclusivity. For now, it is a waiting game to see if/when generic Copaxone comes to market and how many companies will launch. Currently it is predicted that at least two generic companies may be preparing for producing their generic versions of Copaxone. The number of generic manufacturers that enter the market will make a significant difference in how fast the price of Copaxone falls with generic competition.

Because of the interim uncertainty of the exact launch date for generic Copaxone, health care payers must deal with how to best handle the 40mg Copaxone dose. While this new formulation allows less frequent dosing for patients with multiple sclerosis, the efficacy and safety compared to a 20mg once-daily dosing are fairly similar. The new 40mg dosage strength of Copaxone will be protected by a patent until February 11, 2030. While this will not affect the generic availability of the 20mg daily dose product, it will make situations more challenging for patients to switch from the 40mg Copaxone three-times-a-week dosing to the 20mg daily dose in order to take advantage of generic opportunities. There is inconsistency among health care payers that are covering Copaxone 40mg dose.

A best practice is to maintain the 40mg Copaxone dose as non-formulary, in order to steer members/prescribers to the 20mg daily dosing, until generic availability. While this is an advantageous cost saving strategy, the payer also needs to assure that members and prescribers understand the rationale and value in using the 20mg daily dose if they are able, so that they are well-positioned for generics that are hoped to become available soon and lower their out-of-pocket costs in the long term.

NEXIUM OTC

Nexium, a popular medication used for heartburn, became available over-the-counter (OTC) on May 27, 2014. With 2013 global sales of prescription Nexium that reached $7.8 billion and ranked 6th in sales volume worldwide, its OTC availability presents an excellent opportunity for cost savings.

Nexium belongs to a category of medications called proton pump inhibitors (PPIs). PPIs reduce stomach acid production and are used by many individuals to relieve heartburn symptoms and/or for the treatment of other gastrointestinal conditions. For most people, these medications provide similar relief from acid-related symptoms. Nexium joins the ranks of several PPI medications that are already available as OTC products. Three of the six PPIs are available over-the-counter. Additionally, four PPIs have prescription generic equivalents. Dexilant is the only PPI that does not have either a prescription generic equivalent or availability over-the-counter.

Best practice approaches among health care payers today with the availability of OTC Nexium, include:

- Covering Nexium OTC in a manner that aligns with coverage of other OTC heartburn medications in order to encourage patients and their prescribers to switch from prescription to OTC products, when appropriate. Payers that cover OTC PPIs include OTC esomeprazole at a generic copay tier, along with allowing a 42-count package size as an exception to benefit limits on allowed days' supply.
- Updating and/or initiating step therapy on prescription Nexium, as well as Dexilant, requires up to two or three generic prescription/OTC proton pump inhibitors options (e.g. omeprazole, pantoprazole, lansoprazole, and now OTC esomeprazole) that were not effective or not tolerated in treating the patient's condition.
- Continuing to cover prescription generic PPIs for medically necessary treatment of medical conditions that OTC products do not have FDA labeling for use, such as gastroesophageal reflux disorder, peptic ulcers, erosive esophagitis, or Zollinger Ellison's disease. (Note: OTC Nexium only carries FDA labeling for treatment of heartburn, while the prescription product is labeled for treatment of additional medical conditions).

Proton Pump Inhibitor Medications' Availability

Medication Products	Brand Rx Availability	Generic Equivalent Rx Availability	OTC Availability
dexlansoprazole (Dexilant)	Yes	No[1]	No
esomeprazole (Nexium)	Yes	No[2]	Yes
lansoprazole (Prevacid)	Yes	Yes	Yes
omeprazole (Prilosec, Zegerid)	Yes	Yes	Yes
pantoprazole (Protonix)	Yes	Yes	No
rabeprazole (Aciphex)	Yes	Yes	No

1 Brand patent expires December 2020.
2 Patent expired May 2014; however, as of June 26, 2014, generic availability is not clearly known pending final terms of patent infringement settlement.

Health Care payers should consider coverage of OTC medications, when it is consistent with coverage of other OTCs in similar treatment categories as a strategy to reduce pharmacy benefits costs. While payers have speculated on complete coverage exclusion of the PPI medications, because of the large majority of options that are now OTC, this will be challenging as payers still need to assure formulary options that are available for other common gastrointestinal conditions that warrant PPI treatment, but for which OTC products are not specifically labeled. In this case, payers are recommended to continue formulary coverage of at least the prescription PPI generics that will provide the best value overall.

TIMELINE
UPCOMING PART D

August 22-26, 2014	First CY 2015 preview of the 2015 *Medicare & You* plan data in HPMS prior to printing of the CMS publication (not applicable to EGWPs)
August 28-30, 2014	First CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS
August 31, 2014	2015 MTM Program Annual Review completed
Late August/ Early September 2014	Plan preview periods of Star Ratings in HPMS
September 1, 2014	Final date for Part D sponsors to execute and submit a revised Business Associate Agreement (BAA) with the Part D Transaction Facilitation Contractor, NDCHealth dba RelayHealth
September 10-13, 2014	2014 Second CY 2015 Medicare Plan Finder (MPF) Preview and Out-of-Pocket Cost (OOPC) Preview in HPMS
September 16-30, 2014	2014 CMS mails the 2015 *Medicare & You* handbook to Medicare beneficiaries
September 30, 2014	2015 CY 2015 combined Annual Notice of Change (ANOC)/ Evidence of Coverage (EOC) is due to current members. Plans offering Part D must mail their LIS riders and abridged or comprehensive formularies with the ANOV/EOC to ensure current members' receipt by September 30
October 1, 2014	Plans may begin marketing CY 2015 plan benefits
October 1, 2014	Plans must implement changes to Hospice Payment of Part D drugs per July 18, 2014 HPMS memo

About our Authors

About SBG

Solid Benefit Guidance, LLC (SBG) is one of the nation's leading consulting firms and thought leaders in the PBM industry. With more than 130 years of collective experience in this highly complex industry, SBG provides plan sponsors and health plans an unparalleled evaluation of their compliance, pharmacy costs, performance and trends. Some of the services we offer include:

- PBM Procurement & Vendor Oversight
- Compliance Medicare/Medicaid
- PBM Auditing
- Specialty Pharmacy Management Strategy
- Clinical Consulting

SBG experts serve as UL EduNeering's Health Care Library Course authors, and also contribute articles to the Health Care Communiqué.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.