



March 2010 Monthly Newsletter

FEATURED ARTICLES

A Summary of H.R. 3590: Patient Protection and Affordable Care Act

By Jordan Mummau, CIS Compliance Associate

jordanmummau@cis-partners.com

Healthcare Reform is on the tip of everyone's tongue, and the best way to successfully implement the required changes into your company's government and commercial programs is to have a thorough understanding of the [Patient Protection and Affordable Care Act](#). Understandably, that task may seem daunting, considering the Act is over 2,000 pages long. To give our readers the pertinent knowledge they need, we've created the following summary of the Act to highlight the most important and relevant points to the pharmaceutical industry. As always, CIS is here to answer any questions you have about Healthcare Reform and how it affects you.

MEDICARE

2010

- Provide a **\$250 rebate** to Medicare beneficiaries who reach the **Part D coverage gap in 2010** and gradually eliminate the Medicare Part D coverage gap by 2020.
- **Expand Medicare** to individuals exposed to environmental health hazards.

2011

- Manufacturers to provide a **50% discount** on brand-name prescriptions filled in the Medicare Part D coverage gap.
 - Begin phasing-in federal subsidies for generic prescriptions filled in the Medicare Part D coverage gap.
- Provide a **10% Medicare bonus** payment to primary care **physicians** and to general **surgeons** practicing in health professional shortage areas.

2013

- Begin phasing-in **federal subsidies for brand-name prescriptions** filled in the Medicare Part D coverage gap (to 25% in 2020, in addition to the 50% manufacturer brand-name discount).

2014

- **Pilot program** is established; evaluates paying a bundled payment for acute, inpatient hospital services, physician services, outpatient hospital services, and post acute care services.
- **Reduce** Medicare Disproportionate Share Hospital (DSH) payments by **75%**.
 - Increase payments over time based upon the % of uninsured population and the amount of uncompensated care provided.

MEDICAID (Section 2501)

2010

- **Increase** the **Medicaid drug rebate** % for brand name drugs to **23.1%**.
 - **Exception:** rebates for clotting factor drugs and drugs approved exclusively for pediatric use increases to 17.1%.
- **Increase** the **Medicaid rebate** for non-innovator, multiple source drugs to **13% of Average Manufacturer Price (AMP)**.
 - Extend drug rebate to Medicaid managed care plans.

2011

- Prohibit federal payments to states for Medicaid services related to health care acquired conditions.
- State balancing incentive program

2013

- **Increase Medicaid payments** for primary care services provided by primary care doctors for 2013 and 2014 with **100%** federal funding.
- **Reduce** states' Medicaid DSH allotments.

FEATURED ARTICLES

A Summary of H.R. 3590: Patient Protection and Affordable Care Act

By: Jordan Mummau

The House, the Senate, and the States

The Battle for Physician Payment Reporting

By: Gary Miller

Product Attribute Risk and Liability

By: Lauren Pellicciotti
Sabrina Skari

CECs and Unfound Revenue

By: Nicole Arend

CIS': Pharma Compliance InSIGHT: Complimentary Webinar

Continued from Page 1...

2014

- **Expand Medicaid** to all individuals under age 65 with incomes up to 133% Federal Poverty Level (FPL) based on modified adjusted gross income.
- **Reduce** states' Medicaid DSH allotments.

Physician Ownership/Reporting/and Other Transparency - (Section 1128G)

If providing a payment or other transfer of value to a covered entity, a Manufacturer must submit:

- The name of the covered recipient.
- The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
- The amount of the payment or other transfer of value.
- The dates on which the payment or other transfer of value was provided to the covered recipient.
- A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
 - cash or a cash equivalent.
- In-kind items or services.
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
 - Any other form of payment or other transfer of value (as defined by the Secretary).
- A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
 - Consulting fees.
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel (including the specified destinations)
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grant; or
 - Any other nature of the payment or other transfer of value (as defined by the Secretary).
- If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, or to the name of that covered drug, device, biological, or medical supply.
- Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

Monetary **penalties** for non-compliance can range from \$10,000 – \$1,000,000. See section **1128G** if you have specific questions regarding penalties.

More Information:

- Physician-owned hospitals that do not have a provider agreement prior to August 2010 will not be able to participate in Medicare.
- Drug, device, biological and medical supply manufacturers must report gifts and other transfers of value made to a physician, physician medical practice, a physician group practice, and/or a teaching hospital.
- Referring physicians for imaging services must inform patients in writing that the individual may obtain such service from a person other than the referring physician, a physician who is a member of the same group practice, or an individual who is supervised by the physician or by another physician in the group.
- Prescription drug makers and distributors must report to the Health and Human Services (HHS) Secretary information pertaining to drug samples currently being collected internally.
- Pharmacy benefit managers (PBM) or health benefits plans that provide pharmacy benefit management services that contract with healthy plans under Medicare or the Exchange must report information regarding the generic dispensing rate, rebates, discounts, or price concessions negotiated by the PBM.

Continued on Page 3...

Continued from Page 2...

Drug Sampling; Reporting – (Section 1128H)

Beginning in 2012, no later than April 1st of each year each manufacturer and authorized distributor of an applicable drug shall submit to the Secretary the following information from the preceding year:

- In the case of a manufacturer or authorized distributor which makes distributions by mail or common carrier reports:
 - Identity and quantity of drug samples requested and the identity and quantity of drug samples distributed, aggregated by:
 - The name, address, professional designation, and signature of practitioner making the request.
- In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier reports:
 - The identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by:
 - The name, address, professional designation, and signature of the practitioner making the request

Expanded Participation in the 340B Program – (Section 7101)

- **Expansion of Covered Entities** Receiving Discounted Prices – Section 340B of PHS is amended by adding:
 - A **children's hospital** excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act.
 - A free-standing **cancer hospital** excluded from the Medicare prospective payment system
 - **Critical Access Hospitals**
 - **Rural referral centers** (must have disproportionate share adjustment percent equal or greater than 8%)
- Extension of Discount to **Inpatient Drugs**
- Prohibition on Group Purchasing Arrangements
- Medicaid Credits on Inpatient Drugs
 - Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.

Quick Facts/ At a Glance

Dual Eligible Coverage and Payment Coordination –

HHS will establish a Federal Coordinated Health Care office.

- Improve coordination among the federal and state governments for individuals enrolled in both programs.

Medicare Advantage (Part C) –

'MA' payments will be based on the average number of bids submitted by insurance plans in each market.

- MA plans will be prohibited from charging beneficiaries cost sharing for covered services greater than what is charged under fee-for-service.

Medicare Prescription Drug Plan Improvements (Part D) –

In order to have their drugs covered under the Medicare Part D program, drug manufacturers will provide a **50% discount** to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap beginning July 1, 2010.

- Initial coverage limit in the standard Part D benefit will be expanded by **\$500** for 2010.

Pharmacy Reimbursement – (Section 2503)

Use of **AMP** in Upper Limits – Secretary shall calculate the Federal upper reimbursement limit as no less than 175% of the weighted average of the most recently reported monthly AMP for pharmaceutically and therapeutically equivalent multiple source drug products.

- **Smoothing process** will be implemented for AMP
 - Similar to Average Sales Price (ASP) smoothing
- Definition of AMP
 - Wholesalers for drugs distributed to retail community pharmacies
 - Retail community pharmacies that purchase drugs direct from the manufacturer

Continued on Page 4...

Continued from Page 3...

- AMP should **exclude**:
 - Customary Prompt Pay Discount extended to wholesalers
 - Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs.)
 - Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction.
 - Payments received from, and rebates or discounts provided to, PBMs managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy
- **AMP should include**:
 - Any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the AMP for a covered outpatient drug.

Medicare, Medicaid, and CHIP Program Integrity Provisions

The Secretary will establish procedures to screen providers and suppliers participating in Medicare, Medicaid, and CHIP.

- Providers and suppliers enrolling or re-enrolling will be subject to new requirements including a fee, disclosure of current or previous affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a Federal health care program, or has had their billing privileges revoked.
- Secretary of HHS is authorized to deny enrollment in these programs.

Enhanced Medicare and Medicaid Program Integrity Provisions – (Section 1128j)

CMS will include in the integrated data repository (IDR) claims and payment data from Medicare (Parts A, B, C, and D), Medicaid, CHIP, health-related programs administered by the Departments of Veterans Affairs (VA) and Defense (DoD), the Social Security Administration, and the Indian Health Service (IHS).

- New penalties will exclude individuals who order or prescribe an item or service, make false statements on applications or contracts to participate in a Federal health care program, or who know of an overpayment and do not return the overpayment.
- Each violation would be subject to a fine of up to \$50,000.
- The Secretary will take into account the volume of billing for a Durable Medical Equipment (DME) supplier or home health agency when determining the size of a surety bond.
- The Secretary may suspend payments to a provider or supplier pending a fraud investigation.
- Health Care Fraud and Abuse Control (HCFAC) funding will be increased by \$10 million each year for fiscal years 2011 through 2020.
- The Secretary will establish a national health care fraud and abuse data collection program for reporting adverse actions taken against health care providers, suppliers, and practitioners, and submit information on the actions to the National Practitioner Data Bank (NPDB).
- The Secretary will have the authority to dis-enroll a Medicare-enrolled physician or supplier who fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services.
- The HHS Secretary will expand the number of areas to be included in round two of the DME competitive bidding program from 79 of the largest metropolitan statistical areas (MSAs) to 100 of the largest MSAs, and to use competitively bid prices in all areas by 2016.

Continued on Page 5...

Continued from Page 4...

Additional Medicaid Program Integrity Provisions

States must terminate individuals or entities from their Medicaid programs if the individuals or entities were terminated from Medicare or another state's Medicaid program.

- Medicaid agencies must exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that:
 - (1) Has failed to repay overpayments;
 - (2) Is suspended, excluded, or terminated from participation in any Medicaid program;
 - (3) Is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.
- Agents, clearinghouses, or other payees that submit claims on behalf of health care providers must register with the state and the Secretary.
- States and Medicaid managed care entities must submit data elements for program integrity, oversight, and administration.
- States must not make any payments for items or services to any financial institution or entity located outside of the United States.

Pharmaceutical Manufacturers Fee

This provision imposes an annual flat fee of \$2.3 billion on the pharmaceutical manufacturing sector beginning in 2010 allocated across the industry according to market share.

- The fee does not apply to companies with sales of branded pharmaceuticals of \$5 million or less.

Source:

<http://thomas.loc.gov/cgi-bin/query/D?c111:7:./temp/~c111w3XBOt>

The House, the Senate, and the States: The Battle for Physician Payment Reporting

By Gary Miller, CIS Senior Compliance Associate

garymiller@cis-partners.com

Prior to the passing of the Healthcare Reform and Reconciliation Acts:

This year, manufacturers are gearing up for the first full year of new state reporting deadlines for reporting various data in regards to their company's interactions with healthcare professionals (HCPs). With requirements being so inconsistent across state lines, preparation to ensure that the proper processes are in place to collect the correct data has been quite a task. With eight states (including the District of Columbia as a "state") currently having their own form of legislation around reporting requirements, and many more in the works, this difficult task will only grow more complicated. With the future full of inconsistencies, many manufacturers are looking to the federal government for answers; however, things do not get much clearer there either.

Remember the Physician Payments Sunshine Act of 2009? It was introduced in January 2009, and some version of the provision has been in the mix for all the healthcare reform bills developed over the past year. Since the provision has been riding the coat tails of the healthcare reform acts, two versions of the provision have emerged along with the two versions of the healthcare proposals. The Senate version was included in the Patient Protection and Affordable Care Act of 2009 ([H.R. 3590, section 6002](#)) and the House version was included in Affordable Health Care for America Act of 2009 ([H.R. 3962, section 1451](#)).

This raises two questions that have yet to be answered to provide manufacturers with any sense of clarity on the issues:¹ which provisions between the House and the Senate will win out in the end; and ² will the federal law preempt the individual state laws being implemented for reporting? The difference between the House bill and the Senate bill range from a reasonably large disparity in the initial reporting date (the House bill requires reporting and public posting of disclosures by 2011; the Senate bill by 2013) to what information would need to be reported all the way down to who exactly would be required to report it.³

Continued on Page 6...

Continued from Page 5...

Federal law preempting state laws may sound like it will provide relief for manufacturers, but there is some bad news. Although both bills will prohibit states from collecting the same information required to be reported under federal law, they would not stop states from collecting other types of information not captured in or excluded from reporting. Therefore, states could still have their own unique requirements in addition to the blanketed federal reporting requirements, leaving the potential for convoluted reporting requirements nationwide. Recently, there have been some rumors that the provision would preempt any and all state requirements, but history has shown that this will be a tough report to believe to be true. With the Supreme Court ruling last year that FDA approved warning labels do not preempt product liability for additional side effects not listed on a product label (*Wyeth v. Levine*), many believe all preemption scenarios will now play out similarly. Therefore, it is doubtful that any federal Physician Payments Sunshine Act will completely preempt all state reporting requirements.

Pharmaceutical manufacturers should continue to prepare for state level requirements, regardless of the status of the federal Physician Payments Sunshine Act. A solid compliance program and proper preparation will be the only answer to this ever evolving web of oversight and reporting. If you have not already begun to look into the processes needed to be ready for both the existing laws and the soon-to-be regulations, then you should start as soon as possible. CIS has the knowledge and methodologies to address all state compliance concerns, and can ensure that no matter what requirements the House, Senate, or States throw at you, you will be prepared.

References:

¹ [Patient Protection and Affordable Care Act of 2009 \(H.R. 3590, section 6002\)](#)

² [Affordable Health Care for America Act of 2009 \(H.R. 3962, section 1451\)](#)

³ *Bill Comparison*, Prescription Payments Sunshine http://www.prescriptionproject.org/sunshine_act

⁴ Supreme Court of The United States Syllabus; *Wyeth v. Levine* (<http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf>)

Article Update following the passing of the Healthcare Reform and Reconciliation Acts:

Since originally writing this article, at least some of the questions originally posed have now been answered with the passing of the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002), which was signed into law on March 23.

With the Physician Payments Sunshine provisions being included in the reform, we now know exactly what manufacturers will begin to be required to monitor, collect, and report on a federal level. Some of the main points of the provisions are as follows:

- All U.S. manufacturers (and other entities under common ownership) of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or SCHIP must report payments on an annual basis to the department of Health and Human Services, which will post the information on a public website.¹
- The provisions require disclosure of payments (whether cash or in-kind transfers) to all covered recipients including: compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses; charitable contributions; and any other transfer of value as described by the Secretary.¹
- States are prohibited from collecting the same information required to be reported under this section. States may continue to collect other types of data not captured or excluded from reporting (with the exception of de minimis and threshold limits), as well as data for public health purposes or legal proceedings.¹
- Implementation will begin as follows: Starting on January 1, 2012, manufacturers must record all transfers of value. This information is to be reported to HHS by March 31, 2013, and annually thereafter.¹

With some questions answered on a federal level, it will be interesting to see how local state governments react. We can assume one of two scenarios may play out:¹ States may be satisfied by the federal requirements, and either eliminate plans to implement state reporting requirements, and if they currently already have requirements, they may lessen or repeal the requirements completely based on their satisfaction with the federal law; or,² States may make use of the caveat in the law allowing for additional information to be collected on a state level, and continue to require state level reporting for manufacturers.

Continued on Page 7...

Continued from Page 6...

With the federal provisions not implementing a financial limit on manufacturer spending, I would believe that states will continue to implement their power to that end. They will want to confirm compliance with their imposed HCP spend limits, and subsequently manufacturers will need to continue to diligently track and monitor their expenses to ensure they are in compliance. Although the federal reporting will provide some level of consistency, manufacturers should continue working towards an efficient and compliant state reporting program, and ensure they have the proper processes in place to meet all requirements and deadlines. CIS' expertise in this area can assist in ensuring a manufacturer is prepared for both the impending federal requirements, as well as the current state level reporting.

Product Attribute Risk and Liability

By Lauren Pellicciotti, CIS Project Manager

laurenpellicciotti@cis-partners.com

Sabrina Skari, CIS Business Development Manager

sabrinaskari@cis-partners.com

Pharmaceutical manufacturers that choose to participate in the government programs market have always been required to meet several federal and state requirements. However, as the government programs grow and become more complex, the level of scrutiny that is placed on manufacturers and their product data has grown as well. In late 2008, the Senate Finance Committee started to pay very close attention to whether NDCs submitted under a manufacturer are paid for appropriately under the Medicaid Program. Interestingly, the Finance committee's biggest concern was in regard to federal dollars spent on approved drugs. This has an important, and potentially costly, impact on manufacturers because there are frequently inconsistencies in internal source systems. Based on conversations CIS has had with the Centers for Medicare and Medicaid Services (CMS), it is CMS' goal to work with manufacturers to ensure that submitted product data for all covered drugs is accurate and complete. It is with this objective in mind that we have outlined some of the existing product requirements for CMS, as well as they ways they differ from the requirements of other agencies.

First, it is important to acknowledge that various programs and agencies have their own definitions of a "covered drug," as well as varying reporting requirements for these covered drugs. When manufacturers store product information inaccurately, their mistakes can result in reporting errors; these errors increase the likelihood of an agency audit or investigation, and increase the risk of discovering potential False Claims Act (FCA) violations. Accordingly, it should be the goal of every manufacturer to develop a clear and accurate Product Master, that defines covered products and reporting requirements for every program in which the manufacturer participates.

Government programs participation requires that manufacturers abide by the regulations, statutes and guidance outlined by several governing bodies including the Office of Inspector General (OIG), CMS, U.S. Food and Drug Administration (FDA) and the U.S. Department of Veterans' Affairs (VA). The OIG plays the "umbrella" role as far as these governing bodies are concerned, and it is recommended that all pharmaceutical manufacturers abide by the OIG's standards. In addition to the standards set by the OIG, the specific requirements that a manufacturer must abide by when a labeler code or NDC is created are dictated by CMS. These requirements are referred to as "product attributes" and apply to all active drugs on a labeler. They must be provided in order to participate in the Medicaid Drug Rebate Program (MDRP).

Continued on Page 8...



Continued from Page 7...

Product attributes are used for consideration in rebate determination by CMS and the VA. This product information is to be submitted to Drug Data Reporting (DDR) in order to accurately determine rebate amounts. Since the Final Rule of the Deficit Reduction Act ('DRA') was implemented on October 1, 2007 there have been numerous data discrepancies, product category anomalies, and methodology changes at manufacturers which disrupt DDR reporting. The initial product attributes provided to CMS' DDR Center can also be inconsistent with the information stored in internal source systems.

CIS recommends that manufacturers complete an assessment of all relevant product attributes and review *all* applicable source systems in which the product master elements reside in order to accurately report to DDR. The product attribute review should include all CMS requirements.

The CMS required fields are provided below.

Key	Field Name	Definition
1	Labeler Name	Corporate name of entity identified by the labeler code.
2	Labeler Code	First segment of National Drug Code (NDC1) that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.
3	Product Code	Second segment of National Drug Code (NDC2).
4	Package Size Code	Third segment of National Drug Code (NDC3).
5	Drug Category	Classification of drug.
		N = Non-innovator multiple source – Generic
		S = Single source – Brand name
		I = Innovator multiple source – Brand Name
6	DESI Indicator	A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective [LTE]) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs
		Valid Values:
		2 = Safe and effective or non-DESI drug
		3 = Drug under review (no NOOH issued)
		4 = LTE/IRS drug for SOME indications
		5 = LTE/IRS drug for ALL indications
		6 = LTE/IRS drug withdrawn from market

7	Drug Type Indicator	Indicator to show whether this drug product can be acquired only by prescription Valid values: 1 = Rx, 2 = OTC
8	Termination Date	Date drug was withdrawn from market or shelf life of last lot sold if no longer
9	Unit Type	Basic measurement that represents the smallest unit by which the drug is Valid Values: AHF = refers only to injectable Anti-Hemophilic Factor units CAP = Capsule SUP = Suppository GM = Gram ML = Milliliter TAB = Tablet TDP = Transdermal patch EA = EACH (Refers to drugs not identifiable by any other unit type)
10	Units Per Package Size	Total number of units, as defined in the Unit Type field, in the smallest
11	FDA Approval Date	Date of FDA Approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer.
12	Market Entry Date	If marketed prior to 10-01-1990, first date of the first month that the drug was
13	Product Name	Product name as it appears on the FDA registration form.

During an internal evaluation of product attributes among source systems, it is important to ask some key questions:

- Where does the product information reside internally? Is there a master source? Is there a policy related to changing product information, including designation of a key individual who is in charge of monitoring the data?
- Are any of the products listed in the master discontinued?
- Are products classified correctly (i.e. branded vs. generic, single- source vs. non-innovator)
- What is the internal risk that correlates with incorrect Drug Category code assignments?
- Is the GP group coordinated with the regulatory group in terms of product information

All of these questions can help clarify risks associated with product attributes, as any incorrect submissions increase manufacturer liability. However, issues related to the Drug Category Code can provide the greatest internal risk. For example, if a company launches a new brand, typically the Drug Category code assigned would be an "S" for Single-Source drug. This assignment would require the calculation of a Best Price for that drug. However, if the manufacturer mistakenly assigns "N" for Non-Innovator as the code, the company is *not* required to calculate a Best Price. The fact that the code was assigned incorrectly implies that calculations are also being done incorrectly which could have tremendous financial costs associated with this type of negligence. However, the lack of industry guidance and conformation among these practices causes confusion among many manufacturers.

Continued on Page 10...



Continued from Page 9...

The following is a list of best practices that should be implemented internally at all pharmaceutical manufacturers. Their implementation, along with a full product assessment, will create internal alignment to avoid the risk of non-compliance and penalties.

RECOMMENDED BEST PRACTICES

- Step 1: Locate all source systems where a Product Master resides
- Step 2: Run a sales reports for the past 5 years to see what products were sold directly to customers
- Step 3: Review product attributes to determine discrepancies and attribute gaps
- Step 4: Verify all of the Medicaid package sizes
- Step 5: Create a report and remediation plan to depict the inconsistencies and solutions
- Step 6: Investigate each of the required fields to ensure accuracy
- Step 6: Align all source systems
- Step 7: Reach out for guidance regarding any major data discrepancies

This process may seem menial and time-consuming- especially if you work at a pharmaceutical manufacturer that has been operating with several source systems and has not run into any specific issues yet, without having completed an assessment. However, ensuring that your data is entered correctly and aligns among internal source systems will provide a strong foundation for all future participation in government programs and minimize the risk of penalties. This is particularly true as healthcare requirements continue to change and evolve. If there is a policy which specifically outlines a methodology for updating, changing or adding data there is no reason why this process should have to occur more than once internally at any pharmaceutical manufacturer. It will provide a seamless transition into many other GP related activities, including:

- Government calculations
- Federal Supply Schedule submissions
- GP Assessments
- Internal and External Audits

Many of the aforementioned service offerings consider key assumptions that the data is “clean” and accurate. Anomaly discoveries mid-project can result in several hours, and sometimes weeks, of work that is out of scope which may also be associated with high and unforeseen costs. In addition, the additional work required to clean up years of data can change a project’s timelines and affect internal goals and budgets.

In an era of healthcare reform and constant change, it is more important now than ever to ensure that all data that is maintained internally can be successfully used and implemented for use in government programs, calculations and contracts. If you have any questions about the information reviewed in this article, please contact us and we would be happy to provide specific recommendations for your situation. At CIS, we can complete the product attributes assessment for you or we can assist you in the process of scrubbing the data during other related projects. In any regard, we look forward to helping your company maintain compliant activity in participation with all government programs.

Source:

<http://www.cms.hhs.gov>

CECs and Unfound Revenue

By Nicole Arend, CIS Project Manager

nicolearend@cis-partners.com

Imagine this scenario: a national catastrophe has hit late on a Friday night causing total devastation; a message is placed by the military to the Defense Supply Center Philadelphia (DSCP). The message calls for urgent supplies. The DSCP sends a purchase order to CEC holders for products to be shipped within a 24 hour period. Based on the contractor's CEC agreement, the shipment is made. The contract holder has been paid for the level of inventory held and has now received a Purchase Order (PO) for the same product to replenish the stock; the government even pays overnight shipping costs. Entering into a CEC agreement can equate to "unfound revenue" for manufacturers and vendors, so let's take a closer look at this process.

First, what is a CEC? It is a Pharmaceutical Corporate Exigency Contract, which is a partnership between the DSCP and manufacturers, where the government buys access to a large supply of medical items and pharmaceuticals in the event of an emergency or natural disaster.¹

A CEC is just one piece of the government's Emergency Readiness Program within the Department of Defense (DoD). The Pharmaceutical CEC is held at the DSCP, which has specific needs of pharmaceutical and medical equipment and supplies for the readiness program in the event there is a catastrophe declared by the President of the United States. The U.S. Naval Ship *Comfort* was deployed to the Gulf Coast following the devastation of Hurricanes Katrina and Rita, and more recently, to provide humanitarian assistance in Haiti. The *Comfort* was stocked with supplies from vendors that are CEC contract holders to provide care to the injured. The supplies included the necessities for surgical procedures, post-op care, etc. The *Comfort's* pharmacy was fully stocked with all of the medications you would expect to find in any major hospital.

Just as any hospital houses a variety of departments, there are a full range of services and specialties aboard the *Comfort*, including radiology, laboratory, medical supply, pharmacy, physical therapy, burn care, dental and optometry. All of these departments require supplies from vendors!

Without these DSCP CECs in place, the government would not be able to respond rapidly to a crisis as a search would have to be made for vendors that can provide the needed supplies. Should a called-upon vendor not have the products that are needed, time is taken to locate the next vendor, and the next. This would be very inefficient and costly to taxpayers. Placing an emergency order with a vendor that may hold the inventory levels the government is seeking for pharmaceutical and medical supplies is very unlikely, hence, the CEC contract.

The program is beneficial to both the government and the vendor. The vendor is the warehouse for the government without the cost of leasing a building, hiring staff for inventory control, expiration date management, a shipping department, inventory restocking, and disposal of out-of-date products.

Supplies are held by vendors (manufacturers or distributors) at inventory levels requested by the DSCP. The contractor is paid for holding inventory levels for preparedness in the event of a catastrophe. The vendor holds this inventory level for a particular period of time based on the contract. During that period, the government pays a dollar value based on product quantity and type. Vendor quarterly inventory reports are sent to the DSCP to ensure that the agreed upon inventory levels are available. Vendors are sent a payment for the inventory on a quarterly basis. Then, when the government is in need of supplies for an emergency, expedited deliveries are arranged to ensure products are delivered and loaded onboard in time for the ship's departure. This is "unfound revenue" for the vendor, meaning that the vendor is paid quarterly just to keep the required products on hand at the agreed upon inventory levels.

Orders are not just placed for catastrophic emergencies; the CEC is also utilized by the various branches of the armed services. The military makes a purchase for the products on the CEC for the readiness program. Combat zones and any other military readiness fields utilize the CEC program through the DSCP's purchasing system. The contract shipping agreement with the vendor is that products purchased on the CEC are delivered within six business days [2]. The U.S. Armed Services are in need of product and the DSCP manages the product anticipation needs with vendors to ensure our U.S. Armed Forces are provided with the necessary products in a timely manner.

In summary, this program is in fact a safety stock management program. As the manufacturer, you get paid for managing the inventory of your product and for any sales for the products that are on your contract. For many companies that hold a Pharmaceutical Corporate Exigency Contract, it has translated to unfound revenue. CIS' Government Contracting team has the knowledge and experience to help your company participate in CEC agreements. If you are interested in participating, or have any questions, please contact me at nicolearend@cis-partners.com

Pharma Compliance INSIGHT:

Join CIS as we Navigate the Regulatory Landscape GOVERNMENT PROGRAMS - FREE WEBINAR SERIES

Is your company prepared to respond to an OIG audit? Would you be able to answer the agency's questions and to demonstrate your compliance with the statutory requirements? Or, would the audit uncover gaps in your documentation and processes?

Join Compliance Implementation Services for a **complimentary** online discussion about what it means to be "audit-ready." Learn best practices tips to prepare your company for the possibility of a Government audit.

Webinar Title: GP Audit-Ready

Date: Thursday, April 22, 2010

Time: 2:00 PM - 3:00 PM EDT

After registering, you will receive a confirmation email containing information about joining the Webinar.

Space is limited.

Reserve your Webinar seat now at:

<https://www1.gotomeeting.com/register/375905937>



<http://gp.cis-pcx.com/>

<http://clinical.cis-pcx.com/>

<http://sales.cis-pcx.com/>

You are receiving this newsletter because you signed up for it online.

If you would like to subscribe or unsubscribe, please contact us at cispcx@cis-partners.com.