



January 2010 Monthly Newsletter

FEATURED ARTICLES

CMS Issued Release #80 on January 5th - Updated Guidance on Recalculations

By Chris Cobourn, CIS VP Regulatory Affairs

chriscobourn@cis-partners.com

The recent Manufacturer Release # 80 from CMS provided an updated guidance on methodology-related Average Manufacturer Price (AMP) and Best Price (BP) recalculations in the Medicaid Program. As you can see below, there have been various regulations (CFRs, including the Final Rule) and guidance (Release Letters) published to provide manufacturers with information on performing recalculations and restatements. This guidance is designed to help manufacturers understand all the “ins and outs” of these calculations, including what may constitute a methodology change, versus a data-related calculation error. There will be a panel discussion at [IIR Government Programs and Pricing Summit](#) in Baltimore this February (during the February 8th pre-conference day) that will focus on recalculations and restatements. CMS will be participating in the panel discussion, and I think it will be a great opportunity to review the relevant regulations and guidance in effect now, as the rules and processes have changed significantly since Release #14 (the Office of Pharmacy Affairs (OPA) will also be present to discuss the impact of recalculations on the PHS program).

With that said, let me provide some thoughts on my reading of Release #80, starting with a summary of previously published regulations and guidance. Please remember that these are my thoughts and opinions, for discussion purposes, not intended to represent the view of CMS, to be legal advice or provide specific recommendations. I welcome any follow up questions. (FYI, I have a quick summary at the end).

First, let's summarize a few key documents prior to Release #80 (you can also read Debbe Saez's previous blog entry, [“AMP and BP Methodology Changes Are a Go.”](#) for additional information).

[Release #14](#) (January, 1995):

This release provides standard guidance applied to recalculations and restatements, requiring CMS approval prior to a manufacturer making any methodology changes (retroactive or prospective), until Release #78 and the Final Rule made substantive changes to the process.

[Release #61](#) (Sept 2003):

This release references [CMS-2175-FC: REGULATION ISSUED AUGUST 29, 2003](#), which states that manufacturers must report revisions to AMP or BP within a period not to exceed 12 quarters from the quarter in which the data was due (establishing the 12 Quarter rule).

[Release #78](#) (June 26, 2007):

This release states that a manufacturer may implement pending recalculation requests (which were submitted prior to Release # 78, and required CMS approval according to Release #14) on a prospective basis, beginning with the date the manufacturer notified CMS of the recalculation. Release #78 also includes the following provisions:

- Manufacturers may implement the new methodology prospectively as of the date of the request (where the request pre-dates Release #78);
- New recalculation requests, as of the date of Release #78, may proceed with implementation of the change in methodology without review or approval by CMS;
- Manufacturers must notify CMS and receive authorization in advance of retroactive changes in methodology, and include fiscal magnitude and reasons for the change.

[42 CFR Part 447: Medicaid Program; Prescription Drugs; Final Rule](#) (AMP Final Rule, effective October, 2007):

The AMP Final Rule establishes:

- A 3-year window for restatements;
- That revised calculations must be reported for a period not to exceed 12 quarters;
- That manufacturers must report revisions to AMP except where the revision is solely related to lagged price concession data.

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Spotlight on the Policy and Reimbursement section of [CMS' website](#) (August 26, 2009):

- Requests submitted to CMS **before** the 12-quarter limitation took effect: *Retroactive requests for methodology changes may be implemented, without prior review and approval from CMS, for the period specified in the request;*
- Requests submitted to CMS **after** the 12-quarter limitation took effect: *Manufacturers may implement changes and recalculate for a period not to exceed 12 quarters.*

[Release #80](#) (January, 2009):

Release #80 appears to reiterate recent guidance on the 12-quarter period and CMS approval.

Manufacturers with pending recalculation requests, made prior to the effective date of regulations that set the 12-quarter time limitation for submission of recalculated data (which I assume is August, 2003), may implement the revised pricing methodology for the specified periods without prior review and approval by CMS.

- Requests made prior to the guidance establishing the 12-quarter "window" may proceed without prior approval by CMS
- Request for methodology changes received after the establishment of the 12-quarter window may proceed with the change without prior CMS approval (reiterating Release #78), and the period may not exceed 12 quarters (Release #78 did not specifically mention the 12-quarter period).
- A future recalculation may be done without review and approval by CMS, but the manufacturer must notify CMS of the change in methodology, the revised AMP and BP data, the fiscal magnitude and the reason for the change. The change cannot exceed 12 quarters from the date of notification.

A summary, from my perspective:

We can talk about the history of guidance, and where newer guidance may supersede previous guidance, as well as specific times where older guidance may still be in effect if not specifically changed. But, at the end of the day, I think our ultimate goal is to understand the rules that are currently in place. With that said, my initial reading of the status of recalculation requests, as of Release #80, is (again, this is my read of it!):

- The 12-quarter rule should apply to both methodology related changes and data calculation errors;
- Pending recalculation requests made prior to the implementation of the 12-quarter rule may proceed without review or approval, for the period indicated in the request;
- Pending requests issued after the 12-quarter rule was implemented may proceed without further review or approval, and can go back 12 quarters from the date the request is issued; for methodology changes, rationale and impact must be submitted;
- Future recalculation requests, methodology- or data-related, may proceed without further review or approval, and can go back 12 quarters from the date of the request; for methodology changes, rationale and impact must be submitted.

It is also important to review Release #80 for the reiteration on CMS' view on record retention and the 10 year rule, as well as the view that CMS is not expressing an opinion as to whether the revised pricing calculation is consistent and correct.

Thank you, I welcome your questions, and I hope to see you in Baltimore February 8th!
Chris

For all Drug Manufacturer Releases, check out the GP Pharma Compliance Exchange:

http://gp.cis-pcx.com/federal-agencies/centers_for_medicare_and_medicaid_services,8/medicaid_guidance,62/drug_manufacturer_releases,151/

Who Ya Gonna Call? (Not Ghost Busters...)

By Bill Baxter, CIS Strategic Advisor, Government Affairs

billbaxter@cis-partners.com

Hello All! I know many of you will be attending the upcoming IIR GP Summit in Baltimore from February 8th to the 10th (<http://www.iirusa.com/gp/welcome.xml>). CIS is kicking off the Summit with a reprise of last year's popular pre-conference "Town Hall" format and GP 201 presentations, which include many speakers from key federal agencies. This is an excellent opportunity to interact with important policy and operational leaders. Hope to see you there!

Note: If the Summit is not on your schedule but you would like information about it, including a 25% registration discount, please send me an e-mail at billbaxter@cis-partners.com.

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In order to prepare you for GP 201, for those of you who's smiling faces we will see in February, and to provide valuable reference for those not attending the Summit, I have taken the time to compile a summary of important agency information, facts, and websites. In today's fast changing healthcare market, access to key program information and points of reference is vital, so you may find the following listing of some of the most important reference sites helpful:

Centers for Medicare & Medicaid Services (CMS) Home: <http://www.cms.hhs.gov/>

CMS' Mission: To ensure effective, up-to-date health care and to promote quality care for beneficiaries.

CMS' Vision: To achieve a transformed and modernized health care system.

CMS' Strategic Action Plan Objectives:

- Skilled, Committed, and Highly-Motivated Workforce.
- Accurate and Predictable Payments.
- High-Value Health Care.
- Confident, Informed Consumers.
- Collaborative Partnerships.

CMS: Medicare: <http://www.cms.hhs.gov/home/medicare.asp>

A health insurance program for:

- People age 65 or older.
- People under age 65 with certain disabilities.
- People of all ages with End-Stage Renal Disease.

Medicare coverage includes:

Part A- Hospital Insurance - Part A helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). It also helps cover hospice care and some home health care.

Part B - Medical Insurance - Most participants pay a monthly premium for Part B, which helps cover doctors' services and outpatient care. Other medical services that are not covered by Part A are also included, such as some of the services of physical and occupational therapists and home health care providers.

Part D - Prescription Drug Coverage - Most beneficiaries pay a monthly premium for this coverage, which provides insurance for prescription drug coverage and is available to everyone with Medicare. Private companies can also provide this coverage. Beneficiaries choose a drug plan and pay a monthly premium. If a beneficiary chooses not to enroll in a drug plan when first eligible, they may pay a penalty to join later.

CMS: Medicaid: <http://www.cms.hhs.gov/home/medicaid.asp>

- Medicaid is available to certain low-income individuals and families who fit into an eligibility group determined by federal and state law. Medicaid does not reimburse eligibles; but rather pays health care providers directly. Some states require co-payments.
- Medicaid is funded by the federal government and states, and is a state administered program. Each -state sets its own guidelines regarding eligibility and services. Certain requirements must be met, and are listed on the Medicaid website.
- **Medicaid Drug Rebate Program (MDRP)** <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/> is an important part of Medicaid. Created by the Omnibus Budget Reconciliation Act of 1990 (OBRA'90), it requires a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS). The MDRP is administered by CMS' Center for Medicaid and State Operations (CMSO). Two individual teams (Operations (mdroperations@cms.hhs.gov) and Policy) provide guidance on successful and compliant participation in MDRP. Further, the drug rebate program was amended by the Veterans Health Care Act of 1992 (VHCA) and requires a drug manufacturer to have Veteran's Affairs (VA) and Federal Supply Schedule (FSS) agreements to maintain Medicaid participation.

CMS: Children's Health Insurance Program (CHIP): (<http://www.cms.hhs.gov/home/chip.asp>) is a state and federal partnership that targets uninsured children and pregnant women in families with incomes too high to qualify for most state Medicaid programs. The Children's Health Insurance Program Reauthorization Act of 2009 (<http://www.cms.hhs.gov/CHIPRA/>) reauthorized CHIP and funds it through Fiscal Year 2013.

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Health Resources and Services Administration (HRSA): (<http://www.hrsa.gov/>) is an agency of the U.S. Department of Health and Human Services (HHS). It is the principal Federal Agency charged with increasing access to health care for the medically underserved. HRSA's programs are designed to increase access to care, improve quality, and safeguard the health and well-being of the Nation's most vulnerable populations.

Examples of HRSA programs and activities include:

- Providing support to nearly 3,600 health center sites serving about 12.5 million people;
- Funding care and treatment services for an estimated 533,000 people living with HIV/AIDS;
- Assisting states and communities, including rural and border areas, and health care organizations in improving services to women and children;
- Overseeing the national system that allocates organs, tissue, and blood stem cells for transplant;
- Working with academic health centers and other training programs to enhance the diversity and distribution of the Nation's health care workforce;
- Implementing comprehensive systems of services in communities to meet the many needs of children and youth with special health care needs and their families; and
- Participating in global health initiatives such as the President's Emergency Plan for AIDS Relief.

Office of Pharmacy Affairs (OPA): (<http://www.hrsa.gov/opa>) is a component of HRSA Healthcare Systems Bureau. OPA has four primary functions:

- Administration of the 340B Drug Pricing Program, through which certain federally funded grantees and other safety net health care providers purchase prescription medication at significantly reduced prices.
- Maintenance of the membership list of eligible entities.
- Development of innovative pharmacy services models and technical assistance.
- Service as a federal resource about pharmacy.

OPA emphasizes the importance of comprehensive pharmacy services being an integral part of primary health care, which includes:

- Access to affordable pharmaceuticals;
- Application of "best practices" and efficient pharmacy management; and
- Application of systems that improve patient outcomes through safe and effective medication.

See the following segment on the VA for additional specifics about the 340B program. Further, a helpful resource is the site for OPA databases: <http://opanet.hrsa.gov/opa/Login/MainMenu.aspx>

Veterans Health Care Administration: (<http://www.va.gov/>) MDRP was amended by the Veterans Health Care Act of 1992 (PL 102-585) (<http://www.hrsa.gov/opa/pl102585.htm>), and requires a pricing agreement with HHS for the 340B Drug Pricing Program. VHCA requires drug manufacturers to enter into various agreements with the Department of Veterans Affairs (VA) in order to have its drugs covered by Medicaid.

- The following provides an excellent government program glossary for your reference: <http://www.hrsa.gov/opa/glossary.htm>
- Pricing is calculated according to the following document which spells out Non-FAMP requirements: http://www1.va.gov/oamm/docs/business/19971016_AnnualGuidance.pdf

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The sources for this blog as well as much more detailed information can be found via the websites illustrated for each agency above.

Medical Devices for Beginners

By: Gary Miller

CIS Senior Compliance Associate

garymiller@cis-partners.com

What constitutes a Medical Device? According to the Food and Drug Administration (FDA) website, “Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of a medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers (1).”

Lesson One – Who Regulates?

Companies who manufacture, repackage, relabel, and/or import medical devices sold in the United States are regulated by the FDA’s Center for Devices and Radiological Health (CDRH). Recently, medical device regulators have come under fire after a small group of internal whistleblowers from the CDRF alleged that high officials “coerced and intimidated staff into modifying device evaluations (2).”

As with pharmaceutical drugs and biologics, medical devices are also overseen by International Conference on Harmonisation (ICH) regulations and European Commission (EC) directives.

Lesson Two – What are the Basic Regulations?

The Medical Device industry is regulated by a small core group of regulations, from the FDA, EC, and ICH. As with pharmaceutical drugs, there are additional guidance and directives; however, those listed below are the foundation of the regulatory and legislative framework.

FDA:

- Establishment Registration – 21 CFR Part 807
- Medical Device Listing – 21 CFR Part 807
- Premarket Notification 510(k) 21 CFR Part 807 Subpart E
- Premarket Approval (PMA) – 21 CFR Part 814
- Investigational Device Exemption (IDE) – 21 CFR Part 812
- Quality System Regulation (QS) / Good Manufacturing Practice (GMP) – 21 CFR Part 820
- Labeling – 21 CFR Part 801
- Medical Device Reporting – 21 CFR Part 803 (3)

EC:

- 90/385/EEC – Active Implantable Medical Devices
- 93/42/EEC – Medical Devices
- 98/79/EC – In Vitro Diagnostic Medical Devices (4)

ICH:

ICH GCP (E6) Guideline (5)

These are the basic regulations supporting the oversight of the medical device industry. Now, we’ll look at how medical devices are classified, and the regulatory differences between these classifications.

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Lesson Three – Medical Device Classifications

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. The panels include:

- Anesthesiology,
- Cardiovascular,
- Clinical Chemistry and Clinical Toxicology,
- Dental, Ear, Nose, and Throat,
- Gastroenterology and Urology,
- General and Plastic Surgery,
- General Hospital and Personal Use,
- Hematology and Pathology,
- Immunology and Microbiology,
- Neurology,
- Obstetrical and Gynecological,
- Ophthalmic,
- Orthopedic,
- Physical Medicine, and
- Radiology.

Medical devices are then classified into three levels: Class I, II, and III. Within those three levels, there are varying degrees of Regulatory Controls. They are as follows:

1. Class I General Controls

- With Exemptions
- Without Exemptions

2. Class II General Controls and Special Controls

- With Exemptions
- Without Exemptions

3. Class III General Controls and Premarket Approval

General Controls, as noted above, are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

Classification is based on two prominent factors, intended use (indications for use) and risk. The risk the device poses to the patient and/or the user is a major factor in the class that it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk (6).

Lesson Four – Premarket Submissions

There are two main premarket submissions required for manufacturers to submit before receiving approval to market their device. These submissions are based upon Classification and whether the device is exempt or not.

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The first of the two submissions is the Premarket Notification (510(k)). Each individual or company who intends to market in the U.S. a Class I, II, or III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to the FDA unless the device is exempt from 510(k) requirements of the FC&P Act. The purpose of a 510(k) premarket submission to the FDA is to demonstrate that the device to be marketed is at least as safe and effective (known as substantially equivalent (SE)), to an already existing legally marketed device. Manufacturers submitting a 510(k) must compare their device to one or more similar legally marketed devices and prove that their device is a substantial equivalent. Before marketing a device, each individual/group submitting a 510(k) must receive an order, in the form of a letter, from the FDA which finds the device to be SE and states that the device can be marketed in the U.S. (7).

The second submission is a Premarket Approval or PMA. Class III medical devices require a Premarket Approval. The FDA defines Class III devices as "those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury." The PMA is used as the FDA's process of scientific and regulatory review to evaluate the safety and effectiveness of the devices. The data required and reviewed by the FDA includes information from areas such as Non-Clinical Lab Studies and Clinical Investigations. If the PMA is approved by the FDA, then the applicant is permitted to market the device in the U.S. (8).

Recently, the FDA announced a public meeting to discuss the key challenges related to the premarket notification. Also, in September 2009, the agency announced it had asked the Institute of Medicine (IOM) to conduct a comprehensive study of the process, but that study is not expected to conclude until early 2011. Meanwhile, the FDA has begun an internal investigation of their own agency to "evaluate and improve the quality and consistency of the agency's decision-making in the 510(k) process as well as its administration of the program." Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, said of the meeting, "It's been more than 30 years since the establishment of the premarket notification process for medical devices. We are looking forward to hearing from the public on issues related to this program to help us improve it." The FDA receives more than 3,000 510(k) submissions each year (9).

For further information and detail regarding the topics discussed above, please visit the source of this information from the following sites:

References

- (1) <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/default.htm>
- (2) <http://www.genomeweb.com/blog/cdrh-director-resigns-corruption-allegations>
- (3) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>
- (4) http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/index_en.htm#h2-guidance
- (5) http://www.ich.org/UrlGrpServer.jsr?@_ID=276&@_TEMPLATE=254
- (6) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>
- (7) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>
- (8) <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>
- (9) <http://www.medicalnewstoday.com/articles/177000.php>

Additional Sources:

The Medical Device Act of 2009, Gregory D. Curfman, Stephen Morrissey, Ph.D, and Jeffrey M. Drazen, M.D., April 9, 2009; <http://content.nejm.org/cgi/content/full/360/15/1550>
FDA to Review Medical Device Approval, Alicia Mundy, September 23, 2009; <http://online.wsj.com/article/SB125373783403135059.html>

CIS ComplianceWatch: Your Compliance-Monitoring Solution

By: Jess Ebert

CIS Compliance Associate

jessicaebert@cis-partners.com

Compliance Programs are an extremely valuable and necessary component of any pharmaceutical business, as they lay the foundations that promote adherence to applicable federal statutes and regulations. Amidst fraud and abuse, increased scrutiny of corporate conduct, and the considerable amount of expenditures for prescription drugs, it is more important than ever to have a solid, effective Compliance Program.

In May 2003, the Office of Inspector General (OIG) released its guidance for pharmaceutical manufacturers on developing, implementing and monitoring an effective Compliance Program.

According to [the OIG Compliance Program Guidance for Pharmaceutical Manufacturers](#), the seven fundamental elements to an effective Compliance Program are:

1. Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines; and
7. Responding promptly to detected problems and undertaking corrective action.

The first three elements are fairly straightforward: developing and implementing applicable policies and Standard Operating Procedures (SOPs), identifying a corporate compliance committee responsible for operating and monitoring the program, and ensuring that all applicable employees are routinely trained and educated on all aspects of the program. Unfortunately, the work does not stop there. The last four elements all tie into the auditing and monitoring process, because after all, how effective is a Compliance Program that is not being enforced and continually refined?

The first question may be “How does a company combine these four components to ensure that the most comprehensive auditing and monitoring program is in place?” However, there are many more questions that follow, such as “How do I track which employees are continually non-compliant?” “How can I tell if a non-compliance issue is due to a deficiency in the program or with employee competency?” “How can I track if the appropriate corrective or disciplinary action has been taken, or if the issue is still unresolved?” “How should I use the information collected from monitoring and auditing to identify gaps in the Compliance Program?”

All of these questions can be answered using ComplianceWatch, CIS’ innovative new compliance-monitoring tool.

How Does ComplianceWatch Work?

Non-compliant activities, along with other relevant information, such as the date the incident was opened and the severity level of the infraction, tailored to specific company and departmental policies and procedures, are captured for each individual. All of this information can be easily and efficiently entered into the database, where it is compiled and utilized to create compliance reports.

How Can ComplianceWatch Support My Organization?

The reports that are generated by ComplianceWatch will help you assess your entire compliance program on an individual, district or company-wide basis. You will be able to quickly identify open incidents, the disciplinary actions associated with these incidents, and the status of corrective actions being taken, allowing for the escalation of disciplinary action in the event that individuals are repeatedly non-compliant. Using these reports can help identify gaps in your program and trend the frequency of certain incidents, giving you the information you need to continually monitor and improve your Compliance Program.

Who Can Use ComplianceWatch?

ComplianceWatch can be utilized by Corporate Compliance, Sample Accountability, Human Resources and Legal Departments. Because this tool is so versatile, it can be tailored to suit your existing auditing and monitoring processes. It is perfect for small companies with limited resources, as well as large companies who have the daunting task of monitoring thousands of employees.

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Utilizing ComplianceWatch helps ensure compliance with the OIG's Guidance:

Communication: "Reported matters that suggest substantial violations of compliance policies or applicable Federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. The compliance officer should maintain a detailed log that records such reports, including the nature of any investigation, its results, and any remedial or disciplinary action taken [1]." The detailed infraction form and database capture all of that information, allowing for both the employee and the responsible manager to document the issue, as well as the appropriate disciplinary and corrective actions.

Internal Monitoring: "The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and provide these assessments to company's senior management and the compliance committee [1]." The reporting features in ComplianceWatch allow for trend analysis of repeatedly non-compliant employees, infractions that are occurring at regular frequencies that could indicate an issue with policies and procedures, as well as help detect gaps in overall program, all in an easy-to-read format that can be generated within seconds.

Enforcement: "A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect [1]." The ComplianceWatch tool makes it easy to track and follow-up on disciplinary actions (as clearly outlined in company policy and procedure), as well as document the progress of corrective actions. Once your employees see that you are taking compliance seriously, they will take it seriously too.

Quick Response: "...Upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and, if so, take decisive steps to correct the problem [1]." ComplianceWatch captures all of the necessary information to allow you to quickly document the incident and the associated disciplinary action so you can start moving toward corrective actions.

It's important to note that the OIG's guidance is not mandatory, but rather provides solid direction for the establishment and implementation, or reassessment, of a Compliance Program. However, there are many states, such as California (who actually do require compliance programs to be in accordance with the OIG's guidelines under their [Health and Safety Code](#)), that require program audits and investigation of non-compliant behaviors.

ComplianceWatch is your compliance-monitoring solution for tracking non-compliance and disciplinary actions within your organization. Business rules that adhere to the OIG's Guidance are built right into the database to help ensure your company's compliance with the Guidance. ComplianceWatch is ready to be implemented and easy to install (the database requires Microsoft Access 2007), with limited application maintenance, and no ongoing fees. The database can be tailored to fit your specific company-wide or departmental policies and procedures.

For more information on ComplianceWatch, or to schedule a demonstration, please contact Steven Moore, Director of Business Development at stevenmoore@cis-partners.com.

Sources:

(1) The OIG Compliance Program Guidance for Pharmaceutical Manufacturers
<http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

(2) California Health and Safety Code, Section **119400-119402**
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=119001-120000&file=119400-119402>

Letter from GP SME Chris Cobourn, CIS' VP, Regulatory Affairs

chriscobourn@cis-partners.com

Healthcare Reform Legislation and the Senator Brown Effect- What Should GP Professionals Be Thinking Now?

Dear Readers,

Many in the industry are asking the obvious question, "What does it mean to Healthcare Reform now that Republican Scott Brown won the Senate seat in Massachusetts?" While it certainly appears that major legislative action will change direction, I think it is also important that we keep in mind that change is coming and we must be prepared.

I am of the personal opinion that substantial changes to Government Programs for Pharmaceutical Manufacturers are still coming sooner rather than later. There are large and contentious issues in the political debate around Healthcare Reform in the United States, such as the creation of a Public Option and potential taxes on expensive "Cadillac Plans." There is little national debate over some substantial changes that would dramatically impact the industry, such as changing the definition of AMP, raising the base Medicaid rebate percentages (percent of AMP), expanding eligibility and changing the 340B program. The pharmaceutical industry itself seems to have accepted that these changes are coming and are bracing for the financial impact, while also focusing on other open issues in the debate, such as the creation of a period of exclusivity for bio-equivalent drugs.

The next important question is, "Which of the financial components, such as raising the base rebate percentage, will be included in the budget process or in other, newer and maybe smaller bills?" I think that it is still prudent to anticipate that changes to core elements such as methodology, processes and systems will have a dramatic impact on the business. Some changes to core elements that, I believe, will be incorporated in the future include:

- **Changes to the definition of AMP resulting in a Higher AMP.** A shift to a more restrictive definition of "community retail pharmacies", as well as a reduction in the types of rebates that are excluded from AMP can result in a higher-calculated AMP.
- **An increase in base rebates.** Such as 23.1% for Branded Products, 13% for Generic Products and 17.1% for Pediatric Products.
- **Higher Medicaid Rebates.** An increase in the base rebate percentages will lead to a higher percentage on a higher AMP.
- **Medicaid Eligibility will be expanded.** The first two bullets will result in a higher Unit Rebate Amount (URA) and the number of eligible participants will increase based upon expanded eligibility in the states.
- **Medicaid level rebates will be expanded.** Expand the Medicaid Rebates to Managed Care Organizations (MCO) and to Dual Eligibles in Medicare Part D programs.
- **Base-line AMP will be applied to new formulations.** The perceived "loophole" of some new formulations setting their own new Base-line AMP will be addressed, with a major financial impact to many manufacturers.
- **340B Program participation will expand.** Program enhancements seem to be a certainty, with increased eligibility for additional entity types. Further, the potential impact from the changes in AMP and URA from the Medicaid side should be considered. The expansion will also have an impact on GPO purchasing.


Again, I think many, most, or all of the above items should stay on your radar. It is your role as a GP professional in the organization to keep the business informed. These changes run broader and deeper than the Final Rule. As much as the Final Rule had a deep impact, I think that the organizations saw it mainly as a compliance and operational challenge, and not a major impact on the business itself. The changes above may have a dramatic financial impact on your business and change the view of the Government Market. There may be those on the business side that saw the news of Brown's election last week and are thinking that change is not as imminent as they may have thought. We have to identify the relevant stakeholders across the organization and keep them informed of the changes that might still occur. Although I believe that it is still very much a guessing game, I think the dust will settle in the near future on some components of Healthcare Reform, as they have a significant budget impact at the Federal and State levels.

Regards,

Chris Cobourn



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