December 2009 Monthly Newsletter

FEATURED ARTICLES

VETS-100A Report

By Nicole Arend, CIS Project Manager

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Are you a Federal Supply Schedule (FSS) contract holder? Are you seeking an FSS contract?

Compliance with the VETS-100 Report is mandatory for contractors and subcontractors that currently hold a government contract with the value of $100,000 or more awarded or modified on or after December 1, 2003, and it is mandatory that all vendors register prior to an award of an FSS contract as outlined in the National Acquisition Center (NAC) FSS Solicitation.

The U.S. Department of Labor (DOL), Veterans' Employment and Training Service (VETS) is responsible for administering the requirement that Federal contractors and subcontractors track and report annually to the Secretary of Labor the number of employees in their workforces who belong to the categories of veterans covered under the Vietnam Era Veterans' Readjustment Assistance Act of 1974 (VEVRAA) Act.

Federal contractors and subcontractors completing the VETS-100A Report are to provide information on the number of employees and new hires during the reporting period who are:

(1) Disabled veterans;

(2) Veterans who served on active duty in the U.S. military during a war or campaign or expedition for which a campaign badge is awarded;

(3) Veterans who, while serving on active duty in the Armed Forces, participated in a United States military operation for which an Armed Forces service medal was awarded pursuant to Executive Order 12985; and

(4) Recently separated veterans (veterans within 36 months from discharge or release from active duty).

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The annual report is mandatory for compliance. Whether a contractor/Vendor employs Veterans and/or non Veterans, all contractors with a contract value of $100,000 or more and all vendors seeking an FSS contract must complete and file the VETS-100 Report. A copy of the report can be found at https://vets100.vets.dol.gov/VETS-100a.pdf The VETS-100A Report must be submitted no later than September 30th of each year following a calendar year, upon award.

The VETS-100A report can be filed electronically at www.vets100.com.

Federal Contractor Reporting Requirements can be found at http://www.dol.gov/vets/contractor/main.htm#23.

If you have any questions regarding the VETS-100A report or need assistance in completing the report, please contact Nicole Arend at 269-679-3532 or nicolearend@cis-partners.com.

Senator Grassley Saving Billions

By Scott Hoffman, CIS Senior Compliance Associate

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Whenever I read political news I am always fascinated by the sheer amount of dollars discussed. The most recent balance that caught my attention was $98 billion in improper Medicare and Medicaid payments made during fiscal year 2009 [1]. When I first read that number, I failed to grasp how much money it actually represents. Once I took a step back, I realized that particular amount of money represents over 10% of the total healthcare reform bill which has recently been passed by the Senate. I wanted to try and frame how much a billion actually is, so I decided to find an analogy that represents something a little more tangible, because I imagine no one reading this actually has a billion dollars. What I found was that one billion seconds ago, the year was 1977. One billion minutes ago, the year was 102 (that's not a typo) and one billion hours ago, it was the Stone Age [2]. The previous analogy was developed by an advertising agency in 2003, but I did some rough math to update for today's date.

In light of the $98 billion of waste and fraud in the Medicare and Medicaid programs, Sen. Charles Grassley has stepped up and proposed new legislation called the Fighting Medicare Payment Fraud Act of 2009 (the Act). In regards to current federal law requiring very short government turnaround times for Medicare payments, Sen. Grassley said, "Because of this prompt payment rule, the government puts itself in a position of having to pay and chase Medicare fraud, instead of working to prevent it in the first place. That doesn't make any sense, and it's no way to manage Medicare's resources [3]." The Act would give the Secretary of Health and Human Services (the Secretary) up to one year to inspect any claims from any category of supplier or service providers deemed by the Secretary to have a likelihood of fraud, waste or abuse [4].

Another stipulation in the Act requires experts in the Office of Inspector General (OIG) to recommend specific categories of providers or suppliers where additional scrutiny is needed, before payments are made under the prompt payment rule. In order to ensure action is taken based on the OIG's recommendations, the Secretary would be required to provide a response to the Inspector General on how the recommendations would be followed [3]. Sen. Grassley said,

> "We've seen in reports revealed this fall how the Department of Health and Human Services turned a blind eye for many years to alerts from the Inspector General about Medicare fraud. This provision in the bill is intended to make sure the Department of Health and Human Services can't get away with ignoring those kinds of alarms [3]."

With government health spending at roughly $2 trillion last year, and increases projected at 7.1% annually for Medicare, Sen. Grassley's Act is very timely [3]. He has demonstrated his ability to reduce fraud through legislation. In 1986, Grassley authored legislation to fight government contractor fraud; to date the legislation is still the government's most effective tool against healthcare fraud [3]. His qui tam amendments to the False Claims Act, which empowered whistleblowers, have returned roughly $22 billion to the federal Treasury that would have almost assuredly been lost to fraud [3]. Although the proposed legislation will slow down the reimbursement process, I think the money saved will be well worth the additional effort.

Sources:
[1] http://www.healthleadersmedia.com/content/242319/topic/WS_HLM2_FIN/Obama-Plans-to-Sign-Executive-Order-to-Target-Medicare-Waste-Fraud.html
[2] http://www.snopes.com/inboxer/trivia/billions.asp
[3] http://finance.senate.gov/press/Gpress/2009/prg111609a.pdf
[4] http://finance.senate.gov/press/Gpress/2009/prg111609c.pdf

Increased Regulation of Clinical Research in India and China

By Suma Kallurkar, CIS Senior Project Manager

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In recent years, India has become a very popular location for pharmaceutical manufacturers to outsource clinical research and development activities. One such key activity is the conduct of clinical trials. India offers efficiencies in the conduct of clinical trials that Western pharmaceutical manufacturers find difficult to achieve in their home countries. India offers advantages in several areas: volume of patients/subjects, low costs, scientific skills and expertise (including a vast number of hospitals, doctors, and medical schools), and a supporting regulatory environment.

India has taken significant steps in the last few years to strengthen its regulatory environment. In July 2007, the Indian Council of Medical Research's (ICMR) National Institute of Medical Statistics (NIMS) established the Clinical Trials Registry – India (CTRI) - an online registry of clinical trials conducted in India. However, registration with the CTRI was voluntary. The Drug Controller General of India (DCGI) had for a long time been working toward making clinical trial registration mandatory and, finally, these efforts came to fruition earlier this year. It became mandatory for all clinical trials initiated after June 15, 2009 to be registered in CTRI. The mandatory registration requirement calls for clinical trials to be registered prior to enrollment of the first subject.

With the establishment of the CTRI and mandatory requirement for clinical trial registration, India aims to provide greater transparency to the public. Registration also confers greater credibility to those conducting clinical trials and allows them to build and maintain their reputations as quality researchers with high standards and ethics. The most significant impact of mandatory registration may be on Clinical Research Organizations (CROs). Many pharmaceutical manufacturers outsource clinical trials to CROs in India based on the advantages described above. For these pharmaceutical companies, the mandatory registration requirement helps reduce their compliance risk by holding Indian CROs more accountable and making the conduct and results of their research apparent.

India provides an example of the increased globalization of clinical research and the important role of regulation in those countries where clinical research is outsourced. China is another increasingly popular country for outsourcing clinical research and is India's primary competitor in this realm. China also understands the importance of better regulation of CRO activities. China is the process of establishing its first industry standard for CROs. The document *Guidelines for Clinical Trials Services of Contract Research Organizations* has been drafted and may be finalized and made official by the end of this year.

India and China currently represent approximately a 2% share of the pharmaceutical outsourcing market, but are expected to grow at a fast pace in the coming years. As pharmaceutical manufacturers aim to streamline operations and reduce costs, they will continue to look more and more toward outsourcing clinical trials to CROs in countries like India and China that offer much-needed efficiencies. As a result, a pharmaceutical company's compliance risk can now extend off-shore. This makes the current trend in increased regulation and process standardization in these countries a reassuring one.

Sources:
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Medicaid Managed Care: The Other Side of the Counter

By Kyle Hodgin, CIS Compliance Associate

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For those of us involved in Government Programs (GP) compliance, there is a certain side of the Medicaid Drug Rebate Program (Medicaid) that we identify with. The activities we facilitate and participate in culminate in the ultimate exchange of therapeutic substances and cash. Some activities govern the exchange, (calculations resulting in reimbursement amounts), while other activities result from it (Medicaid claims submitted after patients receive medication). There are stock words associated with the world of Medicaid that have become second nature to us such as: “claims,” “wholesalers,” “concessions,” “chargebacks,” and “rebates.” Anyone who has had the pleasure of attending one of CIS’ GP-101 presentations may have had the opportunity to witness a vast, swirling myriad of transactions punctuated by smokestacks and dollar signs in a slide aptly labeled, “Follow the Dollar, Follow the Pill.” This single, seemingly chaotic picture (albeit highly accurate and masterfully constructed) portrays the arena in which we participate; a somewhat “behind-the-pharmacy-counter” perspective that most people are not privy to.

However, there is another side to Medicaid that expands far beyond a unit of medication. Would you associate words such as, “X-ray,” “hospital inpatient services,” “HIV/STD testing,” or even “abortion” with Medicaid? Many of you might, but maybe that is because you are slightly more “seasoned” in Medicaid. Some Medicaid Managed Care programs date back to the 1980’s, and since that time, states have been seeking new ways to reallocate Medicaid funds in order to provide better health care coverage, not just medication, to Medicaid enrollees. Some programs, such as New York Medicaid Managed Care, offer nearly the entire gamut of services from outpatient primary care, to inpatient hospitalization. Many seem to associate the Medicaid program with pills and injections; however, Medicaid does include surgery and approximately 70.9% Medicaid enrollees in the U.S. are enrolled in a Medicaid Managed Care program**.**

While these programs do provide a source of health coverage to vulnerable populations like the disabled, children, low-income families, and the elderly, states still struggle with the coexistence of provision and cost containment There is one state; however, that is being heralded by many as a beacon of hope in an ever-conflicted landscape of cost vs. savings. The Community Care of North Carolina (CCNC) managed care arrangement, which was instituted in 1998, has shown promising signs of increased quality, and increased savings to the Medicaid program. Enrolled patients have access to a Primary Care Physician (PCP) who is essentially their family doctor. This “medical home concept” has provided an established source of care for enrollees while increasing quality of care by encouraging community involvement across social service and health departments, as well as physician networks and hospitals. Case management has also been one of the pillars of the cost savings. Extremely at-risk patients, such as people with chronic illness are an intense focus of case managers in order to keep down costs. A large proportion of these patients are on eight or more prescription medications. CCNC is currently casting a scrutinizing eye on prescribing behaviors of physicians and encouraging increased use of generics where available.

The organization even published a Prescription Advantage List (PAL), which conveniently lists medications in each therapeutic class from least to most expensive; however, the CCNC website does emphasize that the list is in no way indicative of drug efficacy. Another unique pillar of the cost savings benefit is that the structure was physician-developed. CCNC relied heavily on physicians to not only design, but to implement the plan as well. But how? How could they convince doctors to design something that actually worked better and saves money? Increased fee schedules for physicians could be the answer. Proponents of CCNC realized that better financial incentives could possibly translate to a better program if physicians were given the space to develop a plan.

It is essential to note that CCNC is being applauded by many as an example of what Medicaid Managed Care should be heading towards based on its increased provision and decreased expenditures. While CCNC has saved an estimated $147 million dollars in State Fiscal Year 2007, it amounted to approximately 1.5% of the state’s Medicaid expenditure for the year (over $9.8 billion – a few pennies more than the current value of my retirement portfolio). This represents a modest savings, but still an amount that is significantly measurable. North Carolina is still slightly ahead of the national growth rate in Medicaid spending, so that could diminish the effect of savings realized. Hopefully the increased cooperation across networks and providers, paired with case management and cost-conscious efforts will vault CCNC ahead of the curve in Medicaid savings and performance. While we are doggedly hopeful that states will continue to make cost-effective progress in managed care on behalf of patients and taxpayers, simply realizing the complete nature of services being offered to enrollees opens our eyes to a whole new world within the Medicaid program; one that exists on the other side of the counter. *Continued for Sources..*

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Pharma Compliance Exchange Powered by CIS

Send Your Ideas – CIS' 'Agency Town Hall Forum', Full Day Workshop

IIR's Government Programs Summit

Monday, February 8th

Baltimore, MD

Hyatt Regency Hotel

By: Chris Cobourn

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This will be our 3rd Annual Advanced GP session, with a full day agenda geared towards the experienced GP professional (Monday, February 8th is a pre-conference day, running concurrently to MDRP 101). Our format is an "Agency Town Hall Forum," where we have the opportunity to discuss topical issues with the agencies across the Medicaid, Medicare, VA and PHS programs. We received great feedback on last year's conference from the industry participants, as well as the agency representatives, who all enjoyed the opportunity for open dialog.

At CIS, we work closely with the industry on a variety of GP-related topics, as well as discuss issues directly with the agencies. Prior to last year's conference we provided many of the topics and issues we have worked with throughout the year in order to facilitate a good discussion, and also to inform the audience of certain topics that could not be discussed at that time. As I said, the result was a very open and comprehensive dialogue from all sides.

I invite you to participate this year and encourage you to email me any topic ideas in advance. The source of the topic will be confidential, so no company names will be provided. Please email me at chriscobourn@cis-partners.com

We look forward to seeing you in Baltimore in February!

For additional conference information, please visit the website:

http://www.iirusa.com/gp/welcome.xml

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

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

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