



**Advanced**  
Pharmacy Concepts

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#### *Weekly Update.....*

**APC's White Paper on AWP drug pricing and its contract implications for our clients in *now available*. We've been studying the suit, compiling a thorough and thoughtful synopsis of the issues and how they might affect your plan. Click [here](#) to review.**

#### **Health Policy News:**

Under the umbrella of concerns over Swine Flu cases, the Senate confirmed former Governor Kathleen Sebelius as Secretary of HHS. Newly appointed director of the White House Office on Health Reform, Nancy Ann DeParle, declared optimism about passing comprehensive health care reform legislation this year and referred to a "vigorous" debate on the role of a government run health insurance option while business groups expressed "grave reservations" about public insurance. Congress passed a fiscal 2010 budget resolution, making budget reconciliation a pathway for health reform legislation. The move comes amidst warnings that the reconciliation pathway makes it unlikely bipartisan harmony will prevail. A more detailed budget proposal is expected next week. Meanwhile, Senator's Baucus and Grassley outlined multiple elements to a health reform platform, and politicians questioned whether CMS is up to the overhaul task ahead. Other topics in the news this week included providing incentives to increase payments to primary care providers as well as the need to increase the number of primary care physicians available in order to make successful reform a reality. Cost effectiveness remains an issue as a poll conducted by the Harvard School of Public Health and Kaiser suggests more than half of Americans would trust an independent scientific panel to recommend which medical treatments insurers should cover, while just 42% say they'd trust that decision to a government agency. Last, health information technology remained in the news as Surescripts asked for funding to help drive electronic prescribing in small to medium physician practices and the Agency for Healthcare Research and Quality asked the Office of Management and Budget to approve a project to develop a tool set aimed at guiding providers in implement electronic prescribing systems. This week's New England Journal of Medicine reports less than 2% of the nation's Veteran's Administration (VA) Hospitals have a running electronic medical record system, and many could not afford one. The VA has, however, developed over the past 20 years a system using billions in taxpayer dollars. The software is considered part of public domain, meaning developers can use the code at no cost and add features without restriction. It's projected that even with installation costs the software could be far less expensive than options from private companies. An article in the Wall Street Journal (4/30, Landro) profiles a Texas hospital using the technology.

#### **Insurance Industry News**

**Massachusetts insurance updates:** Patient advocates are pushing to stop insurers from charging based on patient age and analysts note use of emergency departments is up in the state despite mandatory health insurance coverage and attribute the trend to a shortage of primary care physicians.

**Our Take:** We continue monitoring Massachusetts health insurance trends. First, while state law mandates residents have health insurance, it leaves many choosing between costly comprehensive coverage and skimpy plans with high out of pocket costs. Interest groups object to laws that have some seniors paying twice that of their younger peers. They want a reasonably priced offering that factors out of pocket expenses and deductibles into patient costs and doesn't charge based upon age. As for the second issue, emergency visits; in evaluating the impact of mandatory insurance upon emergency department use, analysts report visits were up 7% in fiscal 2006-07. Most relevant, they noted 47% of visits were of a non-emergency nature and conclude simply having insurance coverage is not sufficient; limited access due to a shortage of primary care physicians remains limiting factor.

**PBMs announce earnings and an objection to NextRx acquisition is made.** Medco and Express Scripts (ESI) announced that earnings were up and the National Community Pharmacists Association notified the Federal Trade Commission of its objections to WellPoint's plan to sell its PBM unit to ESI.

**Our Take:** It did not long for the FTC to receive its first letter of objection. The group cites concerns with potential anticompetitive effects from the deal and says it is likely that collusion, adversely impacting consumers and pharmacy small business owners is likely. The group knows that in order to have the FTC weigh in on its behalf it will need to demonstrate that the acquisition is not in the best interest of *consumers*. ESI is likely to counter that it saves consumers money by giving them access to home delivery of lower cost generic drugs. Also this week, both Medco and ESI announced higher than anticipated first quarter earnings,

in part due to rising brand name drug prices, and profit on generic drug margins. ESI increased its projections for the rest of the year.

**Insurers have mixed results as earnings and membership results are reported.** Aetna reported its first quarter revenue was up 11%, and is unique among insurers as it notes a 9% increase in membership.

**Our Take:** Aetna's growth is rare, as the insurer added a couple of key accounts. As a rule, however, most of the nation's insurers report lower earnings and decreases in plan memberships. For example, WellPoint, the largest insurer has lost 500,000 members since the start of the year, with 325,000 of those attributed to workers who lost coverage due to layoffs or because of opting out of coverage. UnitedHealth Group, second in size, reports a drop in membership of 900,000.

**Insurance industry group promotes cost benefit methodologies.** America's Health Insurance Plans, (AHIP) is encouraging pay for performance programs.

**Our Take:** Some see the move as an effort to pre-empt government overtures toward cost benefit analysis. AHIP has been highly vocal in recent months, demonstrating a commitment to reform efforts. The group is on record as encouraging private health plans to boost adherence to evidence based treatment guidelines and to reduce emergency department use through payment reforms. Most significant in its comments, the organization emphasizes the role of private insurers in defining innovative approaches necessary to move health care toward "twenty first century evidence based medicine" and emphasizes the industry has initiated efforts not undertaken by Medicare or other public programs.

**BCBS Michigan is implementing a program to increase payments for physicians in patient centered medical home model.**

**Our Take:** The medical home model has gotten a fair amount of press in the past year and refers to medical practices that include health coaches, nurses, dietitian's electronic health records, wellness strategies and chronic disease management programs. The objective is to improve patient health and minimize ER demands. The BCBS plan will increase payments by 10% to the 1,000 MDs in 300 medical home primary care practices participating in the program. As part of the program, BCBS will announce those MDs that meet the highest standards, with the intent of giving patients information to help in selecting providers. Also this week, four primary care organizations representing a total of 350,000 physicians, released collaborative guidelines to help shape testing of patient centered medical homes. The guidelines are aimed at bringing consistency to what medical home demo projects should include, to outline how practices should be chosen for participation in the projects, to describe the support and reimbursement practices should receive; and to define how data should be analyzed and results distributed. CMS announced a three year project to test the medical home concept in eight sites. The project is awaiting clearance by HHS and the White House Office of Management and Budget.

### Pharmaceutical Industry News

**Follow on biologics legislation remains unresolved and controversial.**

**Our Take:** This subject remains contentious as different interest groups are weighing in on this. The issue has strong support from Waxman, but is competing with other high priority issues facing the Energy & Commerce Committee. The duration of exclusivity for branded products remains an issue. Waxman's been an advocate for a path for follow on biologics and has the position as chairman of the Energy and Commerce Committee to help make things happen. He previously forged a deal that would provide 6 years exclusivity for brand drugs. That is now controversial because of a rival bill offering biologics 14.5 years of exclusivity. The new bill has 64 co-sponsors, compared with 9 for the original bill. In the U.S. there is no regulatory pathway for bringing generic versions of biologics to market, and legislators are painfully aware that generic biotech drugs and their cost savings are popular in Europe where an approval mechanism exists.

**Drug companies continue modifying 'business as usual' as approaches to managing drug pipelines evolve in response to market and regulatory directives.**

**Our Take:** This week Sanofi-Aventis announced it is dropping 14 drugs from its experimental new drug pipeline while reporting a 19% increase in net profit for the first quarter. The firm also acquired Mexican generic drug manufacturer Laboratorios Kendrick, Brazil's Medley SA and a US biotech, BiPar Sciences.

**Direct to consumer advertising regulations still unresolved as an FDA moratorium on Direct to Consumer ads for new drugs remains a possibility.**

**Our Take:** Pharma is waiting to see how new FDA leadership views DTC and remains worried about the possibility of a moratorium on DTC ads for new products. (We previously wrote that a delay in allowing DTC ads for new products was a consideration at the agency.) Pharma has been impressing critics with its argument that banning DTC would fail to pass first amendment scrutiny. The result is that the industry might

be making another scenario more likely. They could end up facing a tax change eliminating the tax deductibility of drug marketing costs. Industry could be given a choice between deducting R&D costs or marketing costs at tax time. The tax write off for drug marketing costs has been a target for industry critics for years. Forcing companies to make a choice would very likely exploit tensions already existing within pharma companies.

#### **Centers for Medicare & Medicaid Services (CMS)**

**Medicare estimates were “optimistic,”** in a March 2008 report, projecting the program would short of funding by 2019. Experts now anticipate the program could become insolvent sometime between 2014 and 2016.

**Our Take:** Medicare trustees are planning to notify congress that Medicare Part A will deplete its funds earlier than anticipated. Health reform experts and politicians agree that Medicare reform is an inherent component of health reform. Cuts to Medicare Advantage are in the works. Medicaid is also on the radar. The program provides health benefits for about 60 million of the nation's poorest and usually sickest citizens, it is historically disliked for its low reimbursement rates to providers. A [study](#) published in Health Affairs this week shows Medicaid reimbursement grew 15% from 2003 to 2008, but fell in real terms because it did not keep up with inflation. Medicaid grew faster than Medicare. Medicaid payments were 69% of the Medicare rate in 2003 and were 72% of the Medicare rate in 2008.

**Florida taking action to control narcotic fraud and abuse,** via a statewide database to track drug purchases.

**Our Take:** Last week Florida made headlines for the level of Medicare and Medicaid fraud in the state. This week, the state House of Representatives has determined it needs to establish a database tracking the purchases of narcotic drugs that will put the brakes on potential drug peddlers who seek pills from multiple physicians. Florida, one of only 12 states without a system in place has become a magnet for drug dealers according to lawmakers.

#### **Food and Drug Administration (FDA), Regulatory and Recalls**

**FDA requires warnings on OTC pain medications and Botox.** The agency has finalized a requirement that over the counter drugs containing non-steroidal anti-inflammatory agents, known as NSAIDs and products with acetaminophen bear warning labels. Prescription drug, Botox must display a black box warning.

**Our Take:** This week the FDA finalized rules requiring intensified warning labels on non prescription pain medications. Patients are warned of risks of stomach bleeding or liver injury for acetaminophen, known most commonly as Tylenol. The ruling also applies to nonsteroidal anti inflammatory drugs including; aspirin, ibuprofen, naproxen and ketoprofen. Products containing these compounds have one year to add warnings to labeling. The warnings were approved by the FDA in 2006, but the recent, final rule gives direction as to labeling. The Botox action is triggered in large part because of increasing use of the anti-wrinkle drug for off label indications. Patients must be warned that the injected drug can be spread to other parts of the body and cause paralysis of muscles used for breathing or swallowing. Most frequently, such side effects occur when higher doses of the drug are administered to treat arm and leg spasms. In the off-label usage, Botox is administered to block nerve impulses to certain muscles causing them to relax.

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