



# Legislative News Update

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## Class Action Lawsuits Pertaining to Prescription Drugs

There are a number of related class action lawsuits about the pricing of hundreds of brand-name prescription drugs. You may be included in one or more of the lawsuits and may have received information about them. We wanted to provide you with some background information and guidance on what you should do if you receive information.

Prescription drug costs are often based on list prices, or benchmarks. The most common pricing benchmark is called the Average Wholesale Price (AWP). Several companies publish the AWP of prescription drugs in printed and electronic databases. Drug manufacturers either provide information used to create AWP's or report AWP's to the companies that publish AWP's.

These lawsuits claim that during the time at issue in the cases, AWP's were unlawfully inflated, increasing the prices of certain drugs. The different lawsuits are listed below:

### Key Facts

- Three pending class action lawsuits
- What you should do if you receive a notice

- *New England Carpenters Health Benefits Fund, et al. vs. First DataBank, Inc. and McKesson Corporation* (FDB Case)

*D.C. 37 Health & Security Plan v. Medi-Span* (Medi-Plan Case)

The First Databank and Medi-Span Proposed Settlements relate to claims of drug pricing inflation on more than 450 drugs by companies who publish drug-pricing data. This applies to AWP pricing between August 1, 2001, and March 15, 2005. For more information, go to:

<http://www.fdbmedispansettlement.com/fdbmedispan/default.htm>

- The McKesson Class Action relates to percentage co-payments for certain brand-name prescription drugs between August 1, 2001, and March 15, 2005. The lawsuit claims that McKesson, a large drug wholesaler, wrongfully inflated the mark-up factor used to determine how drugs are priced.

<http://www.awpclassactions.com/McKessonHome.htm>

- *Pharmaceutical Average Wholesale Price Litigation*

The AWP Track 2 Proposed Settlement involves 11 drug manufacturers and includes refunds to consumers, Medicare recipients, and third-party payers (TPPs). The case involves percentage co-payments for approximately 200 drugs between January 1, 1991, and March 1, 2008. For more information, go to: <http://www.awptrack2settlement.com/>

The first notice you may receive states that you may be included in the class action lawsuit and that you have the right to exclude yourself from the lawsuit. If you elect to stay in the lawsuit, you need do nothing. If you want to exclude yourself, the information will provide instructions on how to do so and the deadline for filing the exclusion. If you exclude yourself, you will not be able to file a claim in any settlement that is determined by the courts. The notice generally includes a scheduled trial date as well.



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The second notice you may receive states that a settlement has been proposed in the class action lawsuit and that you may file a claim if you reimbursed or paid for the prescription drugs that are part of the action. The notice will provide you with instructions on how to file the claim and the deadline for filing the claim. If you are interested in filing a claim, you will be responsible for doing so. Information will be needed from your Pharmacy Benefit Manager (PBM) regarding your claims activity related to the specific prescription drug(s) and to help you determine whether or not to pursue the claim filing.

Please contact your MedCost Benefit Services Account Manager for assistance in obtaining the required documentation from your PBM or if you have questions about any of this information.

## Wellness Programs and the Law

*The idea behind wellness programs* is to encourage healthy behavior, or discourage unhealthy behavior, as a way to keep total health care costs under control. This simple concept is so broad that it eludes easy definition. For example, stocking vending machines in the employee cafeteria with healthier snacks or making walking trails available on the company grounds are forms of wellness plans, but so too are offering employees health insurance premium discounts or other cash incentives to maintain a certain cholesterol level or not smoke.

### Key Facts

- Legislation that affects wellness programs
- What you need to know if you offer incentives/disincentives
- Ensuring your wellness program is not discriminatory

Companies, such as yours, are to be commended for offering incentives for healthy behaviors; however, some wellness plans raise discrimination issues with the law. This communication is being provided to offer guidance and to assist you in developing and maintaining both a lawful and successful wellness plan.

*The newest legislation* to have an impact on wellness programs is the HIPAA Nondiscrimination Rules that were published in final form on December 13, 2006. These rules, among other things, set forth specific guidelines for wellness programs and apply to plans with plan years beginning on or after July 1, 2007; for calendar plan years, the new rules apply on January 1, 2008. The HIPAA nondiscrimination provisions

generally prohibit group health plans from charging similarly situated individuals different premiums or contributions, or imposing different deductible, copayment, or other cost sharing requirements based on a health factor. However, there is an exception that allows plans to offer wellness programs that provide incentives for health behaviors.



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*The final HIPAA Nondiscrimination Rules* define a wellness program as any program designed to promote health or prevent disease and categorizes wellness programs into two types:

1. **Participation-based wellness programs** provide rewards without regard to achieving a health status standard
2. **Standard-based wellness programs** provide rewards based on achieving a particular health standard (or penalizes a participant for not achieving it)

**Participation-based wellness programs** that are made available to all similarly situated individuals are *not* subject to the HIPAA wellness program requirements. Examples include:

- A program that reimburses all or part of the cost for membership in a fitness center
- A health screening program that provides a reward for participation and does not base any part of the reward on outcomes
- A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits
- A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking
- A program that provides a reward to employees for attending a monthly health education seminar

**Standard-based wellness programs** are subject to the HIPAA nondiscrimination rules. An example of a standard-based wellness program is when a group health plan gives an annual premium discount of 20% of the cost of employee-only coverage to participants who adhere to a wellness program that includes achieving a cholesterol count under 200. Standard-based wellness programs such as this must meet five specific conditions:

1. The reward must be no more than 20% of the total cost of coverage (employer + employee contribution)
2. The program must be designed to promote health or prevent disease
3. The program must give individuals an opportunity to qualify for the reward at least once a year
4. The reward must be available to all similarly situated individuals
5. The plan must disclose that alternative standards or waivers are available

Most of these conditions are self-explanatory; however, the fifth condition is probably the most difficult to understand and to administer. In many instances, not every participant will be able to achieve the standard that has been set. In these cases, in order to ensure nondiscrimination, the wellness program must make **alternative standards** available so that all individuals have the opportunity to obtain the reward. A statement to this effect must be disclosed to all participants; this can be accomplished by including a statement in the communication to employees about the wellness plan.

**Example disclosure statement** (general): “If you have a health condition that may prevent you from participation in our wellness program, please contact \_\_\_\_\_ so that we can work with you to develop an alternative standard.”



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**Example disclosure statement** (for the cholesterol standard example provided above): “If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.”

The alternative standard in the above situation may be to have the participant’s physician prescribe a regimen or approach; then if the participant follows that regimen, they would be eligible for the discount. As you can see, the alternatives for meeting the standard may be different for each participant, based on their particular situation. For ease of administration and fairness to all, it might be wise to request that the participant engage his/her physician in developing an alternative standard.

**Health plans are permitted to condition enrollment** into the health plan on certain activities, such as completing a health risk assessment, so long as the health information obtained is not used to deny, restrict, or delay eligibility or benefits, or to determine individual premiums. Health plans may require on-going participation in certain health screenings or a personal care management program in order to receive a discount or reward. In these instances, non-participation in these activities would result in their loss of the discount or reward but not disenrollment from the plan. If you experience ongoing excuses from employees regarding their inability to meet the participation requirements, you may elect to include a statement in your wellness program communications such as, “Lack of certification from your physician regarding your inability to participate in the program will be construed as non-participation and will result in loss of the incentive.”

**Word of Caution:** There are laws, other than HIPAA, that affect wellness program activities. For example, commentators on this subject have cited the Americans with Disabilities Act (ADA) and have indicated that the HIPAA exceptions for wellness programs appear to violate the provisions of the ADA (specifically, with respect to non-participation being involuntary since non-participation may result in a penalty or higher premium). At this time, the EEOC, who administers the ADA, has not rendered an opinion or ruling on the matter. We will continue to follow this and let you know should we learn more about it. On this subject, we advise that you play it safe with your wellness program. If you are using incentives or disincentives, and particularly if you condition enrollment on certain activities, it would be prudent to ensure your program meets the five conditions outlined above, even if your program does not totally meet the definition of a standard-based program.

It has been said that a successful wellness program cannot seem mean, punitive, or heavy handed. The program must be proactive and supportive, rewarding more than penalizing, and include frequent positive communication. **Keep up the good work with your wellness programs, but take the appropriate steps to ensure your program avoids any shred of discrimination.** If you have questions or concerns about any aspect of your wellness plan, contact your MedCost Benefit Services Account Manager.



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## Newborn and Mothers Health Protection Act Final Rules for Group Health Plans and Health Insurance Issuers

This legislation was issued in the form of an *Interim* Final Rule on October 27, 1998; at that time, MedCost Benefit Services made the appropriate changes to communicate and administer the benefit according to the *Interim* Rule. The *Final Rule* was published on October 20, 2008, and is effective for plan years beginning on or after January 1, 2009. The Final Rule supports the Interim Rule in that group health plans and health insurance issuers may not restrict mothers' and newborns' benefits for a hospital length of stay in conjunction with childbirth to less than 48 hours following a vaginal delivery or 96 hours following a delivery by cesarean section. This Final Rule will not affect our current administration of the benefit; it only requires a change in the language in the notice that is required. MedCost will issue a blanket amendment to include the new notice language and will modify our SPD to ensure the language is correct going forward.

### Key Facts

- Pertains to hospital length of stay for childbirth
- Nothing new in the administration of the benefit
- Language in member notice will be amended

## “GINA”

### Genetic Information Nondiscrimination Act of 2008

This legislation was signed into law on May 21, 2008, and applies to group health plans and employers. For group health plans, it is effective for plan years beginning on or after May 21, 2009. For employers, the provisions regarding workplace discrimination are effective November 21, 2009. In a nutshell, the legislation prohibits discrimination on the basis of genetic information with respect to health insurance and employment.

### Key Facts

- Prohibits health plans from using genetic information to determine eligibility or premiums
- Prohibits employers from using genetic information when making employment decisions

The legislation prohibits group health plans from:

- Adjusting group premium or contribution amounts on the basis of genetic information
- Requesting or requiring an individual or an individual's family members to undergo a genetic test
- Requesting, requiring, or purchasing genetic information for underwriting purposes or collecting genetic information about an

individual before the individual is enrolled or covered under the plan.



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For purposes of the legislation, genetic information means information about:

- An individual's genetic tests;
- The genetic tests of the individual's family members; and
- The manifestation of a disease or disorder in a family member.

This includes information about an individual's or family member's fetus or embryo.

The legislation directs Health and Human Services to revise the HIPAA privacy regulations to provide that genetic information is treated as health information (as defined in the privacy regulations) and to prohibit group health plans and insurance issuers from using or disclosing Personal Health Information that is genetic information for underwriting purposes. This may require modification to the Notice of Privacy Practices; however, we will not take action until directives are published by Health and Human Services.

MedCost Benefit Services has analyzed the legislation and has determined that no immediate action is necessary other than a minor revision to the definition of "genetic information" in plan documents. Since the change is not substantive, an amendment will not be required.

## **"Mental Health Parity" The Paul Wellstone & Pete Domenici Mental Health Parity & Addiction Equity Act of 2008**

This legislation was signed into law on October 3, 2008, and is effective for plan years beginning on or after October 3, 2009. The legislation requires health insurance plans that offer mental health and addiction coverage to provide that coverage on par with financial and treatment coverage offered for other physical illnesses. The protections extend to Americans in health plans of 51 or more employees, including those in self-insured health plans. The law does not mandate that group health plans cover mental health or addiction treatment, only that when plans do so, the coverage must be equitable to other medical coverage. The legislation directs the Department of Labor, Health and Human Services and the Treasury Department to issue regulations within a year of the law's enactment to carry out its provisions, although the effective date of the new requirements is not contingent upon such regulations being issued. MedCost Benefit Services has analyzed the legislation and will begin reviewing plan documents to determine what changes, if any, will be required. You will receive more information about this at a later date.

### **Key Facts**

- If health plan offers mental health coverage, that coverage must be equitable to other medical coverage
- Does not require health plan to offer mental health coverage



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## “Michelle’s Law” Continuation of Coverage for Sick College Students

This legislation was signed into law on October 9, 2008, and is effective for group health plan years beginning on or after October 9, 2009; for calendar year plan years, it is effective January 1, 2010. This

### Key Facts

- Pertains to college students who remain on plan while maintaining student status
- Requires continuation of coverage for up to one year if student incurs a medically necessary leave of absence
- Requires certification from attending physician

legislation ensures that dependent students who take a medically necessary leave of absence from a post secondary educational institution do not lose health insurance coverage for up to 12 months after they take the leave of absence. The requirement to extend the coverage applies only if the plan receives a written certification by a treating physician of the dependent child which states that the child is suffering from a serious illness or injury and that the leave of absence is medically necessary. MedCost Benefit Services has analyzed the legislation and has scheduled the first internal meeting to discuss a plan of action for implementation. You will receive more information about this at a later date.

## Department of Labor Issues Guidance on Bonding Requirements for ERISA Plans

ERISA requires that every fiduciary of an employee benefit plan and every person who handles funds or other property of such a plan shall be bonded. The bonding requirement is intended to protect employee benefit plans from risk of loss due to fraud or dishonesty on the part of persons who ‘handle’ plan funds or other property.

Over the past several years, a number of questions have been raised concerning the bonding rules, particularly after the enactment of the Pension Protection Act of 2006. Therefore, on November 25, 2008, the DOL issued a Field Assistance Bulletin (No. 2008-04) intended to provide guidance and help clarify the bonding rules. This is not a new regulatory requirement, only a clarification of an existing requirement.

### Key Facts

- Bonding is required to protect employee benefit plans from loss due to fraud or dishonesty
- Persons who handle funds or make decisions for plan must be bonded
- Required bond amounts vary, but no less than \$1,000/person



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Highlights include:

- If a service provider (such as a TPA or investment advisor) performs duties and functions that involve access to plan funds or decision-making authority that can give rise to a risk of loss through fraud or dishonesty, then the service provider is required to be bonded. Although the plan is not required to purchase the bond coverage for any service provider, the plan's fiduciaries are responsible for ensuring and monitoring that the service provider is properly bonded. **NOTE: Generally, MedCost Benefit Services does not have access to plan funds or decision-making authority for the plan; however, please be assured that MedCost Benefit Services is appropriately bonded.**
- Welfare benefit plans offered through a cafeteria plan under Code Section 125 that are treated as unfunded for Form 5500 reporting will be treated as unfunded for bonding purposes as well. Unfunded plans are exempt from ERISA's bonding requirement (an unfunded plan is one that pays benefits only from the general assets of a union or employer; the assets used to pay the benefits must remain in, and not be segregated in any way from, the employer's or union's general assets until the benefits are distributed).
- Generally, the maximum bond required is \$500,000, but the Pension Protection Act increased the maximum to \$1 million for plans holding employer securities. Each plan official is required to be bonded for at least 10% of the amount he or she handles, but in no event less than \$1,000. The bulletin provides guidance on how to calculate the bond amount when multiple plans are covered under a single bond.
- Regarding bonding relating to members of plan benefit or investment committees, the bonding requirement applies if the committee members handle plan funds or property, and particularly if they make final decisions with regard to benefits or investments. If the committee members only make recommendations that are subject to final approval by someone else, they are not subject to bonding.

The bulletin is in a Q&A format and is quite 'user-friendly'. It can be accessed at <http://www.dol.gov/ebsa/regs/fab2008-4.html>.

If you have questions about any of this information, please contact your MedCost Benefit Services Account Manager.



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## **Massachusetts Health Care Reform “Minimum Creditable Coverage” Regulations Finalized**

An additional component of the Massachusetts Health Care Reform Act has been finalized. You may recall that under the Massachusetts Health Care Reform Act, as of July 1, 2007, all adult residents of the State of Massachusetts, age 18 or older, were required to have health coverage that qualifies as “creditable coverage,” as long as it is deemed affordable by the Massachusetts Health Insurance Connector Authority (“Connector”). The Massachusetts Department of Revenue has enforced this law through state income tax filings. For the tax year 2007, residents who did not comply lost their personal exemption, worth about \$219. This applies to any individual who lives in the State of Massachusetts and can include employees of companies domiciled in other states or participants in self-funded health plans that have been written in other states.

### **Key Facts**

- Applies to plans that have participants who live in the State of Massachusetts
- Plans that meet the standards will help their participants who are MA residents avoid a tax penalty

On October 17, 2008, the Connector finalized additional regulations that define exactly what constitutes “creditable coverage,” which is the minimum coverage that Massachusetts residents must carry in order to avoid a penalty. Beginning January 1, 2009, Massachusetts residents must carry health coverage that provides a minimum of the following benefits:

- Core services: physician, inpatient acute care, day surgery, and diagnostic procedures and tests
- Preventative and primary care
- Emergency services
- Hospitalization
- Ambulatory patient services
- Mental health and substance abuse services
- Prescription drugs must be covered

The regulations elaborate on other areas of coverage including co-payment, deductible and co-insurance amounts, out-of-pocket maximums, exclusions and limitations, and preventive care services.

Beginning January 1, 2010, the minimum creditable coverage requirements will extend a bit farther.

Though group health plans are not required to offer coverage that meets the new minimum creditable coverage standards, plan participants need to know whether their group health coverage meets the standards. If not, they may need to obtain other coverage in order to avoid a tax penalty.



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MedCost Benefit Services has analyzed this legislation and will determine which client group plans have participants who live in the State of Massachusetts. Generally, group health plans administered by MedCost Benefit Services meet the minimum creditable coverage standards. However, if any group health plan with residents in the State of Massachusetts does not meet these standards, MedCost Benefit Services will notify the group.

***Additional Note Regarding 2008 Tax Year:*** For those client group plans that have participants who have been residents of the State of Massachusetts during the 2008 calendar year, MedCost Benefit Services will again provide the required MA1099's. Affected client group plans should expect to hear from us in early January regarding this matter.

If you have questions about this information, please contact your MedCost Benefit Services Account Manager.