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March 2009

PHARMACY BENEFITS MANAGEMENT UPDATE

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Samantha Brown, Esq.



D.C.'s AccessRx Act Preempted by ERISA

On March 19, 2009, the U.S. District Court for the District of Columbia ruled that D.C.'s AccessRx Act has "an impermissible connection with ERISA and is therefore preempted." The AccessRx Act provided that PBMs owe a fiduciary duty to health insurers, ERISA plans, and other "covered entities," and imposed several disclosure requirements on PBMs. In its decision, the Court noted that ERISA's preemption clause is designed to allow for uniform administration of ERISA plans across the nation and to prevent states from subjecting ERISA administration "to the peculiarities of the laws of each jurisdiction." Without deciding whether a PBM constitutes a fiduciary under ERISA, the court noted that "PBMs provide ERISA plans with essential administrative services, which states may not regulate." Thus declining to follow the First Circuit Court of Appeals' analysis in upholding a virtually identical law in Maine, the D.C. District Court found that the AccessRx Act would impede a uniform administration of ERISA plans. The Court also stated that its decision was bolstered by the U.S. Department of Labor's proposed regulation that may require PBMs to disclose conflicts of interest and certain financial information.

AWP Litigation Update

On March 17, 2009, the Court in the Average Wholesale Price (AWP) litigation approved the terms of the settlement agreements entered into between the class plaintiffs and First DataBank (FDB) and Medi-Span respectively. Among the settlement terms are the requirements for both FDB and Medi-Span to adjust to 1.20 the mark-up factor applied to Wholesale Acquisition Cost (WAC) to determine the AWP that they each publish for the approximately 1,400 NDCs that were identified in the plaintiffs' complaint. These adjustments cannot occur for at least 180 days, which is a change from the 90-day period that was originally in the amended settlement.

Additionally, as we outlined in our January 2009 newsletter, independent of the settlement, FDB and Medi-Span have expressed that they intend to (i) apply the same 1.20 markup factor to all other NDCs whose AWP is set based upon a markup to WAC in excess of 1.20 and (ii) discontinue publishing AWP for all drugs within two years. Both companies confirmed these intentions in statements released last week.

Laurel Wala, Esq.



Prescription Drug Importation Bill Introduced

On March 4, 2009, the "Pharmaceutical Market Access and Drug Safety Act" was introduced in the U.S. Senate. The bill allows U.S. licensed pharmacies and drug wholesalers to import FDA-approved medications from FDA-approved plants with comparable safety standards in Canada, Europe, Australia, New Zealand, and Japan and pass on savings to American customers. As written, this legislation would allow Americans to benefit from lower prices in these countries but still enable them to receive their prescriptions at local pharmacies. The bill would also allow individual consumers to purchase prescription drugs for personal use from safe, reliable, FDA-inspected Canadian pharmacies. President Obama has indicated support for this legislation in his 2010 budget proposal.

Cami Agena, Esq.



ABOUT US

The Phoenix Law Group of Feldman Brown Wala Hall and Agena, PLC is one of the few law firms in the country with an entire practice group devoted exclusively to pharmacy benefits and operations. What sets our practice group apart? For starters, it is made up entirely of attorneys that have in-house counsel experience, giving us significant expertise in an extremely complex industry.

Primarily representing pharmacy benefit managers (PBMs) and retail pharmacy chains, we work with our clients daily as an extension of their in-house legal departments. Because we get to know our clients thoroughly, we understand how to achieve their business goals, and are able to provide each with pragmatic advice and workable solutions. From contract development and negotiation, to structuring operations to meet regulatory requirements, our experience allows us to handle a client's needs seamlessly without wasted time getting up to speed.

Bill Introduced To Give Independent Pharmacies More Leverage In Contract Negotiations

The U.S. House of Representative is considering legislation (H.R. 1204) aimed at leveling the playing field between independent community pharmacies on the one hand and insurers and PBMs on the other hand to allow the independent pharmacies to negotiate collectively for prescription provider contracts. The bill that was introduced would make the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers (including health plans under parts C and D of the Medicare Program) in the same manner as such laws apply to protected activities under the National Labor Relations Act.

OIG Report Compares Part D Pharmacy Reimbursement To Medicaid

The OIG has issued a report comparing Part D and Medicaid pharmacy reimbursement amounts, finding Medicaid reimbursement amounts for multi-source drugs were typically higher than for Part D. The OIG report is available at: <http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf>

Medi-Cal Reimbursement Cuts Put On Hold

California statute required the Medicaid agency to implement a five percent reimbursement cut on prescription and over-the-counter drugs effective March 1, 2009. However, a federal district court in California issued a preliminary injunction halting the reimbursement cuts in the Medi-Cal program.

Phoenix Business Journal named The Phoenix Law Group Of Feldman Brown Wala Hall & Agena to the list of largest specialty firms in Phoenix for its Pharmacy Benefits and Operations practice.

For additional information that impacts the pharmaceutical benefit industry, visit PLGTRACK.COM or contact Samantha Brown sbrown@phoenixlawgroup.com, Laurel Wala lwala@phoenixlawgroup.com, or Cami Agena cagena@phoenixlawgroup.com at The Phoenix Law Group www.phoenixlawgroup.com.

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