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April 2009

PHARMACY BENEFITS MANAGEMENT UPDATE

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ABOUT US

Average Wholesale Price Litigation Update

On March 30, 2009, the Court in the First DataBank and Medi-Span AWP class action lawsuits entered its final judgment ordering First DataBank and Medi-Span each to comply with the terms of their respective settlement agreements and dismissing with prejudice all class claims. Between April 2nd and April 6th, four groups of objectors filed various Motions to Stay the Judgment pending appeal to the U.S. Court of Appeals for the First Circuit. First DataBank and Medi-Span have until April 27, 2009 to each file consolidated responses to these motions. It is expected that any appeals to the First Circuit will be filed by the end of this month.

State Legislative Round Up

On a regular basis, we will highlight some new state statutory requirements that we think you may be interested in. To catch you up on changes that have already gone into effect in 2009, below are some noteworthy new requirements:

- *South Carolina* has a new prompt pay law and new restrictions applicable to the recovery of provider overpayments
- *North Carolina* and *Florida* have new uniform prescription identification card laws
- *Kentucky* and *Virginia* laws require that payments to providers be made electronically if requested and if the provider contract requires claims to be submitted electronically
- *New Hampshire* has a new statutory scheme governing prescription account card programs and includes requirements for program registration, program design, marketing, and provider agreements
- *New Hampshire* law now mandates that a PBM or an insurer require a network pharmacy to charge a member or insured the pharmacy's usual and customary price of filling a prescription or the individual's copayment, whichever is less
- *Iowa* law now establishes parameters for pharmacy audits by PBMs.

Additionally, you should be aware of the following requirements that go into effect over the next few months:

- *Louisiana* has new requirements addressing the content and format of pharmacy remittance advices that will go into effect on July 1, 2009
- *Minnesota* has new standards for health care electronic claims transactions, part of which will go into effect on July 15, 2009
- *Vermont's* law specifying under what circumstances a PPBM, insurer, etc. can sell, license or exchange for value regulated records containing prescriber-identifiable data is scheduled to go into effect on July 1, 2009; however the law is the subject of litigation that has not yet been decided.

West Virginia Requiring PBMs to Obtain TPA License

In February 2009, the Commissioner of the West Virginia Office of Insurance issued an "Informational Letter" informing PBMs that it believes that a PBM falls within the current definition of a TPA in West Virginia, and thus must be licensed as such. The West Virginia Senate is currently considering HB 2626, which, if passed, would amend the law to expressly require PBMs to be licensed as TPAs in West Virginia. However, by issuing the Informational Letter, the Commissioner has made it clear that, even if HB 2626 does not become law, the Office of Insurance expects PBMs

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.

to be licensed as TPAs in West Virginia.

Going HITECH

The new Health Information Technology for Economic and Clinical Health Act ("HITECH Act") passed on February 17, 2009, significantly changes the HIPAA landscape for PBMs. PBMs are business associates of the covered entities they contract with (ie, health plans and pharmacies). Some of the biggest changes for PBMs under the HITECH ACT are:

- Business Associates must comply with the HIPAA Security Rule and are now subject to criminal and civil penalty violations of this rule,
- Business Associates are now subject to civil and criminal penalties if they breach their Business Associate Agreement with a covered entity,
- Business Associates are required to take reasonable steps to cure a breach of the Business Associate Agreement by a covered entity, or terminate the agreement with a covered entity to HHS,
- new requirements for notifying covered entities when there is an unauthorized access, use or disclosure of PHI by the Business Associate,
- Business Associate Agreements must be amended to include these new requirements.

There are other changes which may indirectly impact your PBM business. The effective dates for these requirements vary from the date of enactment (February 17, 2009) to 2 years or more after enactment.

CMS Revises 2010 Application Calendar

CMS has announced revisions to the calendar for review and approval/denial of MA, MA-PD, PDP, and Employer Direct applications for 2010. Application communications will be sent electronically for the remainder of the 2010 application review period, so applicants should confirm that email addresses listed in the Health Plan Management System (HPMS) are correct. The revised timeline is as follows:

May 5, 2009 CMS Issues Notices of Intent to Deny for Part C and D (Separate Notices)

May 6 - 15, 2009 (8:00PM EDT) HPMS Upload Window - Applicants may submit revised documents in response to deficiencies identified in the Intent to Deny Letters

May 29, 2009 CMS issues Denial/Conditional Approval Letters (Combined Notices for C and D)

June 1, 2009 (11:59 PM EDT) Bid Submissions Due

June 15, 2009 Deadline for Denied Applicants to Request Administrative Review/Hearing

June 15, 2009 Deadline for Applicants to receive positive determination upon appeal in order to enter into contract for 2010

CMS Announces 2010 Payment Information for Part C Medicare Advantage Plans and Part D Prescription Drug Plans

On April 6, 2009, CMS announced the final payment information for MA Part D plans and Part C MA plan payment information. There are changes from the Advance Notice, especially in the Part D benefit plan parameters. The details can be found at: <http://www.cms.hhs.gov/MedicareAdvtgSpecRateStates/AD/list.asp#TopOfPage>.

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.

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