



THE PHOENIX LAW GROUP OF Feldman Brown Wala Hall & Avena, PLC



| [HOME](#) | [CONTACT](#) | [ATTORNEYS](#) |

In This Issue

[HIPAA/HITECH FINAL RULE](#)

[PROPOSED FEDERAL RULE](#)

[OKLAHOMA BILL](#)

[ABOUT US](#)

March 2013

PHARMACY BENEFITS MANAGEMENT UPDATE

HIPAA/HITECH FINAL RULE

On January 25, 2013, the Office for Civil Rights, Department of Health and Human Services issued a final rule titled, "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules." The Final Rule is effective March 26, 2013. Covered Entities and Business Associates must comply with most requirements of the Final Rule by September 23, 2013; compliance with the required updates to Business Associate Agreements isn't required until the earlier of (1) September 23, 2014 if a Business Associate Agreement was in place on January 25, 2013 that complies with the HIPAA requirements in place on that date and the Business Associate Agreement is not renewed or modified between March 26 and September 22, 2013 and (2) the date that the Agreement is renewed or modified.

The final rule:

- Modifies the Privacy, Security, and Enforcement Rules to strengthen privacy and security protections for health information and to improve enforcement as provided for in HITECH
- Adopts changes to the HIPAA Enforcement Rule to incorporate the increased and tiered civil money penalty structure provided by the HITECH Act
- Includes final modifications to the Breach Notification Rule, including replacing the breach notification interim rule's "harm" threshold with a more objective standard and imposing a presumption of breach
- Revises the HIPAA Privacy Rule to increase privacy protections for genetic information as required by the Genetic Information Nondiscrimination Act of 2008

Covered Entities and Business Associates should be reviewing, as applicable, Notices of Privacy Practices, HIPAA Authorization Forms, Business Associate Agreements, HIPAA Privacy and Security Policies, Breach Notification Policies and Procedures, and HIPAA-related training for required changes to ensure compliance with the Final Rule.

PROPOSED FEDERAL RULE CAPS MA AND PDP PROFITS

CMS issued a proposed rule, which beginning January 1, 2014, caps profit margins for MA organizations and Part D sponsors. Under these new requirements, MA organizations and Part D sponsors are required to report their MLR, and are subject to financial and other penalties for a failure to meet a new statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. This proposed rule sets forth CMS' proposed approach to implement these new MLR requirements for the MA and Part D programs.

Comments to the proposed rule are due to CMS no later than 5 p.m. EST on April 16, 2013.

OKLAHOMA BILL PROVIDES FOR BOARD OF PHARMACY TO REGULATE PBMs

Oklahoma is considering a bill to have the Board of Pharmacy license and regulate PBMs. The House Committee recently voted in favor of the bill, which if passed, would become effective November 1, 2013. Under the draft bill:

- **Licensure.** PBMs must be licensed by the Oklahoma Board of Pharmacy in order to provide PBM services in the state. The Board of Pharmacy could suspend, revoke, or refuse to issue or renew a license for noncompliance by the PBM or for conduct likely to mislead, deceive, or defraud the public or the Board of Pharmacy, or for unfair or deceptive business practices.
- **Disclosures.** The Board of Pharmacy will establish disclosures required for PBMs to make to pharmacies and payors and would allow the Board of Pharmacy to review and investigate records of the PBM. PBMs must provide plans, upon request, with: (i) all claims financial and utilization information, (ii) the difference in the amount paid to providers and the amount billed to the plan, and (iii) if the PBM requires or authorizes a substitution of a drug which costs more than the prescribed drug, the cost of both drugs and any benefit or payment accruing to the PBM as a result of the substitution.
- **Use of Information.** PBMs must notify plan sponsors if the PBM intends to provide, sell, lease, or rent drug utilization or claims data to any third-party. PBMs would be prohibited from providing personally identifiable demographic, drug, utilization, and claims data to an affiliated pharmacy. Members must affirmatively opt-in prior to the provision, lease, rental, or sale of the individual's information to any third-party.
- **Contact with Members.** The bill further prohibits the PBM from contacting members by any means without the express written permission of the plan and the member.
- **Copay Calculation.** When copay is percentage based, PBM must calculate the percentage based upon the amount actually paid to the pharmacy (not the amount paid by the plan to the PBM).
- **Pharmacy Contracts.** PBM must have written contracts with pharmacies that: (i) contain all rates, terms, and condition governing claims payment; (ii) include the basis of the methodology and sources utilized to determine MAC pricing; (iii) require updates to MAC pricing at least every 7 days; and (iv) establish a process for prompt notification of such pricing updates to pharmacies.
- **MAC Pricing.** PBM must maintain a procedure to eliminate products from the MAC list or modify rates timely to remain consistent with pricing changes in the marketplace. PBM must provide a reasonable administration appeals procedures for providers to contest MAC rates. If MAC price is below the provider's invoice cost, the PBM must increase the MAC price and make the change retroactive to the fill date, which change must be effective for all providers. To place a drug on a MAC list, PBM must ensure the drug has at least 3 nationally available, therapeutically equivalent (AA or AB rated), multiple source drug products available (no limitations on distribution; not be obsolete or temporarily unavailable).
- **Pharmacy Accreditation/Licensure.** PBM cannot require pharmacy to be accredited or licensed other than by the Board of Pharmacy or other state or federal government entity.

ABOUT US

The Phoenix Law Group of Feldman Brown Wala Hall and Agena, PLC is one of the few 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 health plans, 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.

For two years in a row, the Phoenix Business Journal has 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.

To join our mailing list, please contact:
sharnagel@phoenixlawgroup.com

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).

The information contained herein is informational only, does not constitute legal advice, and may not be relied on as such. No attorney-client relationship is formed by the provision of this information.

[| HOME | CONTACT | ATTORNEYS |](#)