



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

ACHIEVING | BALANCE

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

January 2009

PHARMACY BENEFITS MANAGEMENT UPDATE

Quick Links

[About Us](#)
[Related Topics](#)

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

Samantha Brown, Esq.



PART D COMPLIANCE REPORTING REQUIRED BY JANUARY 30, 2009

On January 21, 2009, CMS issued a memo to all MA organizations and PDP sponsors and Cost Plans explaining that CMS is requiring these organizations to report their compliance with the Medicare Improvements for Patients and Providers Act's (MIPPA) marketing regulations by January 30, 2009. The required reporting tool may only be submitted electronically. MAs' and PDPs' compliance officers should have received an email from CMS with the link to the reporting tool. If not, the tool can be accessed via: <https://vovici.com/wsb.dll/s/11dc4g398af>.

CMS WITHDRAWS 2010 DRAFT CALL LETTER

On January 22, 2009, CMS announced that it was withdrawing the draft 2010 call letter containing proposed guidance for MA organizations and PDP sponsors. CMS' statement explained, "At this time, we are withdrawing that draft call letter, pending an opportunity for further review of the document." CMS further stated that it will post a new draft "as soon as possible" so that MAs and PDPs will have the guidance they need to prepare their bids by the statutory deadline.

RDS COST DATA SUBMISSION GUIDANCE

On January 12, 2009, CMS published guidance for plan sponsors in the Retiree Drug Subsidy (RDS) program on how to submit cost data for purposes of receiving RDS including how to (1) take into account drug manufacturer rebates and other price concessions, that are retained by a PBM; (2) calculate rebates and similar price concessions and allocate them among unique benefit options by month; and (3) arrange to make drug-specific data available to CMS directly from the RDS sponsor's PBM (or other subcontractors as applicable) in the event the sponsor does not have such data. This guidance modifies guidance published by CMS in June 2008 and clarifies that there is no requirement for a plan sponsor to report manufacturer rebates and similar price concessions that are retained by a PBM for any RDS plan year.

WHITE HOUSE PUTS NEW RULES ON HOLD

On January 20, 2009, White House Chief of Staff Rahm Emanuel sent a memo to all heads of federal executive agencies stating that any regulations released by the Bush administration that have either not been published or have not yet taken legal effect are on hold pending a review by the White House. A list of such regulations was not provided, but the "hold" likely includes U.S. Department of Health and Human Services rules for implementing ICD-10 and new Electronic Transaction Standards under HIPAA. Other recent rules that may be put on hold include CMS' final rule on "lock-in pricing" under Medicare Part D, an interim final rule to identify protected classes of prescription drugs under Medicare Part D and an interim final rule that addresses steps to restart the CMS' competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies.

NEW MANDATORY DISCLOSURES FOR BUSINESSES SUBJECT TO FAR

As of December 12, 2008, certain entities that do business with the

Laurel Wala, Esq.



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.

Federal government that are subject to Federal Acquisition Regulations ("FAR") are required to provide mandatory disclosures for violations of the False Claims Act ("FCA"). (This does not include Part D contracts, but may include Medicaid contracts.) The new expanded disclosure requirement is triggered whenever the entity has "credible evidence" of significant overpayments or certain criminal violations, including False Claims Act violations. Failure to disclose the above violations will constitute grounds for suspension and/or disbarment.

The new provision requires that any contract that is expected to exceed \$5 million and have a performance period of 120 days or more include the mandatory disclosure language found at FAR 52.203-13 (including flowdown to subcontracts). A contractor generally has 90 days from the date of the contract award to establish an internal control system which includes business ethics awareness and compliance programs as well as internal control programs.

For additional information regarding compliance with the new FAR mandatory disclosure requirements, please contact Shari Miller, smiller@phoenixlawgroup.com.

PHARMACISTS IN D.C. WILL BE ABLE TO ADMINISTER VACCINES

The District of Columbia recently passed an amendment to its Pharmacy Practice Act that effectively authorizes pharmacists who are appropriately certified by the Board of Pharmacy to administer vaccines and immunizations pursuant to a written protocol and valid prescription or standing physician's order. The amendment becomes effective after approval by the Mayor (or in the event of a veto, action by the Council to override the veto), a 30-day period of Congressional review, and publication in the District of Columbia Register.

For additional information contact:
Suzanne Broderick (sbroderick@phoenixlawgroup.com), at
The Phoenix Law Group Of Feldman Brown Wala Hall & Agena.

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).

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.

[Forward email](#)

✉ [SafeUnsubscribe®](#)

This email was sent to sbrown@phoenixlawgroup.com by

sbroderick@phoenixlawgroup.com.

[Update Profile/Email Address](#) | Instant removal with [SafeUnsubscribe™](#) | [Privacy Policy](#).

Email Marketing by



The Phoenix Law Group of | Feldman Brown Wala Hall & Agena, PLC | 8765 E Bell Road, Suite 110 | Scottsdale | AZ | 85260