

From: Marsha Walker

Office of the Inspector General

The Inspector General's office told me that giving of formula discharge bags, accepting money from formula companies to give these out and use the formula exclusively, etc could implicate the federal anti-kickback statute as it applied to Medicaid mothers and babies. This may prevent reimbursement from Medicaid, if Medicaid mothers are receiving any of the gifts or are subjected to treatment or care biased as a result of the kickback. In order to remove these bags totally, not just take out the formula sample you have to look to see if the hospital has a contract with the formula company to do this. Then start with a committee or group who collects the data on the harm to breastfeeding from this practice. The Cochrane Reviews show that exclusive breastfeeding is decreased at all times measured between 0-6 months in the presence of the commercial bag, with or without formula. Other data shows that WIC mothers are 6 times less likely to be breastfeeding at 7-10 days in the presence of the bags. Check with the hospital's Corporate Compliance officer to see if accepting bribes violates any compliance rules. Run this by the ethics committee, risk management, and your hospital's CEO/president. Offer an alternative discharge bag. Just a few ideas! Call me at 781 893-3553 if you need more help.

Marsha Walker

Notes from phone conversation with Marsha Walker:

We should contact:

Ethics committee

Is the hospital acting ethically for signing an exclusive contract and taking a bribe (money for education fund) to market a formula company's product?

Corporate Compliance

Check with Corporate Compliance officer to see if accepting bribes violates any compliance rules

Risk Management

Liable for damage for using **ANY** formula (cite risks of formula)

- Need to know high risk of hospital being sued
- Especially with LIPIL
 - Not being informed their baby received "experimental" LIPIL formula

Recalls on formula

- We don't track numbers
- What if formula we hand out in diaper bags is recalled and a baby gets sick?
 - The hospital would be liable
- Cite recent recalls

Area Pediatricians

Ask all area pediatricians whether any side effects have been reported from their patients

- Lipil side effects
- Massive explosive diarrhea

President/CEO

Needs to know what is going on

Mission Statement

Does this practice support our mission statement?

Ideas for other funding of Lactation Department

Get Lactation Department put under community education

- When negotiating contracts with the insurance companies
 - Add reimbursable charges for in-patient LC visits
- Outpatient consults
- Boutique (state how it would be cost-effective to help self-support Lactation Department)
- Rotary Club, Lions Club may help fund department
 - Junior League to help fund “breastfeeding friendly” discharge bags
 - Marketing to help with cost of discharge bags as a marketing tool?

Enfamil Lipil-

Not FDA approved

Institute of Medicine is studying the safety

Investigational

Mom’s need to know the above, this bypasses parental informed consent

Formula rep’s switched to this without asking physicians or OB staff

Risk Management needs to know High risk of being sued

- Because of not being informed their baby received “experimental” formula

Side effects

Massive explosive diarrhea

*All side effects have to be reported

We should have a reporting form posted in the nursery to report the side effects

- Get form on MEDWATCH
- Mead Johnson’s phone number should also be available for reporting

Hospital needs to track the numbers on back of the formula (cite recent recalls)

Mom’s need to know powder formula is not sterile

We should have a list of what to say to mother on the use of formula and Lipil

- When handing out the diaper bags-mom’s need to know the risks of formula use

Our goal as advocates is to educate and use the system to achieve these goals. One way to illustrate the pervasiveness of formula in your hospital is to see how many items from formula companies you can find. Calculate how many advertisements for formula a mother in your hospital sees and how many for breastfeeding. Make sure you bring up the issue of guilt. People use this as an excuse to dodge the issue. There is no data that supports the statement that if we tell mothers about breastfeeding or the hazards of formula that they will feel guilty. We cannot make anyone FEEL guilty. That is an emotion one chooses to feel - like love, hate, anger.

Good luck

Marsha

I can offer no helpful comments on whether this aggressive type of product promotion is medically ethical. If, however, these products were being paid for with Medicaid funds, one might successfully argue, under state law, (Wis. Stat. sec 49.49) that such constitutes an unlawful kickback.

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