

Commercial Discharge Bags

Healthcare Laws, Regulations, Guidelines, and Compliance

Increasing attention is being directed towards compliance requirements in the healthcare and pharmaceutical industries. Some of these regulations have implications for those who purchase, recommend, receive, and/or distribute infant formula. Healthcare recommendations and decisions should be made without financial conflicts of interest or commercial bias. Infant formula is viewed very much like pharmaceuticals for the purpose of compliance with healthcare laws, regulations, and guidelines. As with pharmaceuticals, infant formula is marketed to and through health care professionals, mothers often purchase infant formula based on health provider recommendations, and infant formula is paid for by federally funded programs such as Medicaid and WIC. Therefore, there are a number of laws, regulations, and guidelines that may be helpful to use in your work to eliminate hospital distribution of commercial discharge bags.

The Federal Anti-Kickback Statute is a federal law that makes it a felony to give or receive a “kickback” to induce or reward the purchase of items covered by a federal health care program. Specifically, it prohibits offering, paying, soliciting, or receiving:

.... any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person.... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program....

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U.S.C. § 1320a-7b(b)(2).

This statute may apply to discharge bags because mothers can perceive that they are a recommendation to purchase the product. Mothers may wish to use the product after discharge and such usage may be funded by Federal programs. Thus the statute applies to hospitals and health providers who treat infants eligible for the Medicaid or WIC program. Almost half of the infants in the US are serviced by WIC.

Certain purchasing agreements between hospitals and formula companies also violate this statute, such as offering free samples of one product (infant formula for the nursery) on the condition that the hospital distribute samples (discharge bags) of other products from the same manufacturer. Compensation given to healthcare providers for

recommending products violates this statute. Mothers may perceive that the distribution of formula discharge bags is a recommendation to purchase the product.

The courts have identified a number of considerations that help identify arrangements at greatest risk of prosecution:

- Does the arrangement have a potential to interfere with or skew clinical decision-making? The bags are often part of a hospital culture that requires provider neutrality on infant feeding, preventing providers from unequivocal support of breastfeeding. Bags could be given in lieu of expert lactation care and services
- Does the arrangement have the potential to increase costs to Federal health care programs or enrollees? Discharge bags market the most expensive brands of infant formula. When only these are provided to Federal programs the costs of the formula are increased. Mothers who purchase the formula incur increased costs over store brand formulas
- Does the arrangement raise patient safety concerns? Powdered infant formula in discharge bags is not sterile and can and has resulted in infant infections with *Enterobacter sakazakii*. Lot numbers of formula in the bags are not routinely recorded so parents cannot be informed of formula

recalls in a timely manner. Mothers are not asked if they have a history of allergies or diabetes in the family prior to the distribution of the formula bags. Sensitization of breastfed infants from susceptible families can occur with just one bottle made from this formula

Suspected violations of this statute should be reported to the Inspector General of the Department of Health and Human Services at: esec@os.dhhs.gov

Federal Antitrust Laws are a group of laws insuring fair competition in the marketplace. Some purchasing arrangements between hospitals and infant formula manufacturers may violate antitrust laws. These usually involve agreements (bundling, tie-in) where the hospital receives discounts on one item if it agrees to use that same manufacturer's products from another category

PhRMA Code is a voluntary guide for the pharmaceutical industry regarding relationships with physicians and other health care providers.¹ It was adopted in 2002 in response to closer scrutiny by the federal government of questionable and excessive promotional activities by the pharmaceutical industry. Because it is voluntary and written by an industry that should receive oversight from objective sources, this code remains broad with no penalties or recourse for violations

¹ www.phrma.org/files/PhRMA%20Code.pdf

OIG Compliance Program Guidance

The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued *Publication of the OIG Compliance Program Guidance for Hospitals*,² and *OIG Supplemental Compliance Program Guidance for Hospitals*³ which recommend and model internal compliance programs in hospitals. Other guidance documents were issued for pharmaceutical manufacturers and small-group physician practices. None of these are mandatory. Infant formula companies are specifically mentioned

Health Insurance Portability and Accountability Act (HIPAA)⁴

The privacy rule with HIPAA defines marketing as “making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.” If the communication is “marketing” then the communication can occur only if the covered entity first obtains an individual’s “authorization.” HIPAA however goes on to exempt certain situations from the requirement of prior authorization, even if it is marketing, if it is in the form of a face-to-face communication made by a covered entity to an individual, or a promotional gift of nominal value provided by the covered entity. No prior authorization is necessary “when a hospital provides a free package of formula and other baby

products to new mothers as they leave the maternity ward.” This means that even though discharge bags are a form of marketing, mothers do not have to be informed that the “gift” is actually an inducement to purchase the formula following discharge. Mothers may think that it is a health provider recommendation rather than a sales pitch.

² www.oig.hhs.gov/authorities/docs/cpghosp.pdf

³ www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf

⁴ www.hhs.gov/ocr/hipaa/guidelines/marketing.pdf