

Regulatory Implications of Giving Buzzy® to Patients or Physicians

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1. Current regulations regarding gifts to patients.

1.1 OIG 2002 Special Advisory Bulletin OFFERING GIFTS AND OTHER INDUCEMENTS TO BENEFICIARIES

“Under section 1128A(a)(5) of the Social Security Act (the Act), enacted as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to \$10,000 for each wrongful act.

For convenience, in this Special Advisory Bulletin, the term “provider” includes practitioners and suppliers, as defined in 42 CFR 400.202.

In addition, the OIG does not believe that drug manufacturers are “providers, practitioners, or suppliers” for the limited purposes of section 1128A(a)(5)...” [underlining added]

1.2 OIG 2016 Statement Gifts of Nominal Value

This December 7 2016 document maintains that this rule is relevant to gifts “likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier”. The document increases the nominal value of gifts which can be given to \$15 per item and \$75 aggregate.

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>

1.3 Drug Manufacturers offering gifts to beneficiaries: Currently there are no regulatory guidelines for pharmaceutical companies giving medically related devices, or even gifts, to select patients. Gifts and support are commonly provided to patients with Hemophilia and Juvenile Diabetes.

2. PHRMA Guidelines

While there is a guideline on Ethical Gifts to Physicians, there is no guideline on Ethical Gifts to Patients.

2.1 PhRMA Principles on Interactions with Patient Organizations November 20, 2014

“No company should require that it be the sole funder of the patient organization or any of its programs. Companies that provide financial support or in-kind contributions to patient organizations should have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.”

2.2 Principles on Conduct of Clinical Trials

These revised Principles take effect on June 1, 2015

“Payments should be based on research participants’ time and/or reimbursement for reasonable expenses incurred during their participation in a clinical trial, such as parking, travel, and lodging expenses. Payment may be monetary and/or consist of items of modest value based on the factors noted above.”

2.3 PhRMA Direct to Consumer Advertising Principles – March 2, 2009

“In general, the FDA requires all DTC information: • To be accurate and not misleading; • To make claims only when supported by substantial evidence; • To reflect balance between risks and benefits; and • To be consistent with the FDA-approved labeling.”

No guidance is given on DTC advertising offering tangible support directly to patients to help taking the medication.

3. FDA Guidelines

3.1 “Medical Device Combination Product Guidelines 21 CFR 3.2 (e)

3.2 Definitions. [Underlined Emphasis Added]

... (e) *Combination product* includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.”

3.2 Buzzy® FDA 510K K130631 PHW Indications for Use

“Control pain associated with injections, venipuncture, IV starts, cosmetic injections and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension”

Buzzy is a Class I device – medication or injection substance agnostic.

4. Industry Commentary:

Pharma Marketing Blog Monday May 7 2009 @Pharmaguy

These are proposed rules by a blogger. No commentary was made on this blog.

1. “Any gifts accepted by patients individually or as a group should primarily entail a benefit to patients and should not be of substantial value.
2. Individual gifts of minimal value are permissible as long as the gifts help patients pass the time while waiting in the office. [My interpretation: crossword puzzle books are OK as are patient education materials, and even iPods if they are the cheap Shuffle versions (load 'em up with audio from ads)].
3. Free lunches should be healthy and appropriate for the medical condition of the patient

4. No gifts should be offered with strings attached.
5. Giving gifts to patients should not violate HIPAA privacy regulations.”

5. Current Industry Practice, Gifts to Patients

5.1 Excerpts from Scientific Journal Commentary Gifts to Patients [PLoS Med.](https://doi.org/10.1371/journal.pmed.1001996) 2016 Jun; 13(6): e1001996. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4907439/>

Novo Nordisk supports a Consumer Council, SevenSecure \$500 per child grant program, Baxter funds a hemophilia camp for kids; Pfizer has a Hemophilia Village website offering \$2500 scholarships; Bayer offers an electronic FactorTrack application, Pfizer a HemAware program. The National Hemophilia Foundation has been given \$15MM. Of note, the NHF sponsored a program which gave 100 Buzzy units to each Hemophilia clinic in the country. The paper concludes “Regulatory controls on industry interactions with patients should be considered.” Currently there are no such controls.

5.2 Diabetes gifts directly to patients

Lilly, Bayer, and others donate 20,000 gifts a year to JDRF, who distribute them to patients. The branded gifts include a teddy bear, backpack, and coloring books. There is one medically related nutrition book included.

5.3 Market Trends – Adherence

New adherence gifts at CES 2016 – devices and programs to incentivize adherence

<https://www.statnews.com/2016/02/04/big-pharma-medication-adherence/>

“Danish drug maker Novo Nordisk is taking another tack: It’s working with a company called HealthPrize to promote adherence to diabetes medication, according to HealthPrize’s chief medical officer, Katrina Firlik. HealthPrize encourages patients to document their prescription refills by rewarding them with gift cards or charitable donations.

Industry giants like Merck, Pfizer, and Sanofi, as well as the big industry group, the Pharmaceutical Research and Manufacturers of America, are [backing](#) a lobbying [campaign](#) to, among other things, get regulators to bless bold efforts by drug makers to push patients to take medication. For instance, they want to be able to pay pharmacists to call patients directly.”

6. AMA Code Regarding Gifts to Physicians

“Opinion 8.06 1 - Gifts to Physicians from Industry - Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value.”

Under both AMA and PHrMA 2009 guidelines, gifts valued less than \$100 are allowed if they primarily entail a benefit to patients or are associated with a physician’s practice.