

AFCBB Adoption of the PhRMA and AdvaMed Code

Preamble

The Association of Family Cord Blood Banks (AFCBB) represents the family (private) umbilical cord blood bank industry. Its members offer cord blood processing and storage to families who wish to store their children's cord blood for therapeutic future use of the stem cells contained in the cord blood.

The Association believes that the foundation of public and private cord blood banking rests upon education of both expectant parents and physicians and upon informed consent. Ethical relationships with healthcare professionals are critical to our mission of helping expectant parents by making sure they are aware of their options and have the ability to make an informed choice about the fate of their children's cord blood. An important part of achieving that mission is ensuring that healthcare professionals have the latest and most accurate information available regarding the advances in stem cell therapies and the science of processing and storage of cord blood.

This document focuses on our interactions with healthcare professionals as it relates to the marketing of services. Effective marketing of our members' services ensures that patients have access to services they need and want for their families. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to:

- ❖ Inform healthcare professionals of the advances in stem cell research
- ❖ Inform healthcare professionals of the benefits of members' services
- ❖ Provide scientific and education information
- ❖ Support medical research and education, and
- ❖ Obtain feedback and advice about our services through consultation with medical experts

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. Our interactions with healthcare professionals should be perceived as appropriate by patients or the public at large. This Code reinforces our intention that our interactions with healthcare professionals benefit patients and enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be guided by what is in the best interests of their patients. This principle requires that physicians and other healthcare professionals conduct their practices in a manner that supports this in reality and in appearance. By extension, cord blood banks have an ethical obligation to conform themselves in a manner that supports this underlying ethical principle.

Therefore, the AFCBB endorses and adopts, as its own voluntary Code, the guidance and spirit of the PhRMA Code and AdvaMed Code on relationships with healthcare professionals to the extent that they apply to the cord blood banking business, effective October 1, 2007.*

* This Code and the guidance is offered as guidance only and does not constitute legal advice. Each company should obtain its own legal advice.

**Supplemental Interpretative Guidance:
PhRMA Code and AdvaMed Code**

The questions and answers set forth below accompany the “AFCBB - Preamble to the Adoption of the PhRMA Code and AdvaMed Code,” the “PhRMA Code on Interactions with Healthcare Professionals” (including the questions and answers appended to the Code) and the “Code of Ethics on Interactions with Health Care Professionals” adopted by the Advanced Medical Technology Association (the “AdvaMed Code”). These four documents are the operative interpretative guidance for AFCBB member companies with respect to their interactions with healthcare professionals.

1. Who are “healthcare professionals”?

The term “healthcare professional” includes any person who is involved in the direct or indirect provision of healthcare services to families during the course of a woman’s pregnancy. This definition is meant to be broad and includes clinical and non-clinical people who fit within the above description.

2. May a member company pay healthcare professionals to collect data or information?

Yes. Payments to healthcare professionals for the collection of data or information are acceptable if (a) a legitimate need for the data or other information is clearly identified in advance of requesting the data or other information and entering into arrangements with healthcare professionals for the collection,(b) the criteria for selecting the healthcare professionals to provide the data or other information is directly related to the purpose of collecting the data or other information, and the persons responsible for selecting the healthcare professionals have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria,(c) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose,(d) the amount of data or other information collected is not greater than the amount of data reasonably necessary to achieve the identified purpose, and (e) the amount of the payments represents fair market value for the services rendered and is not tied to the volume or value of business generated by the healthcare professional on behalf of the member company. In addition, member companies should regularly review their utilization of the data and other information collected in order to verify that they have a legitimate need for continuing to collect the data and other information.

3. May a member company pay fair market value to healthcare professionals for providing collection-related services on behalf of his/her patient?

Yes. Payments to healthcare professionals for collection-related services are acceptable so long as the (a) arrangement is documented in writing in advance of the healthcare professional rendering the services and the documentation includes the amount that will be paid for the services, (b) the amount of the payments represents fair market value for the services rendered and is not tied to the volume or value of business generated by the healthcare professional on behalf of the member company, (c) the arrangement does not contain competitive limitations, such as an agreement that the healthcare professional will only provide the services for the member company, and (d) the member company discloses to its customers that healthcare professionals may be paid by the member company to provide collection-related services.

4. May a member company pay fair market value to healthcare professionals for providing legitimate consulting and other services to the company?

Yes. Payments to healthcare professionals for consulting and other services are acceptable so long as the (a) a legitimate need for the services is clearly identified, (b) the arrangement is documented in writing in advance of the healthcare professional rendering the services and the documentation includes the amount to be paid for the services, (c) the criteria for selecting the healthcare professionals to provide the services is directly related to the services being provided, and the persons responsible for selecting the healthcare professionals have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria, (d) the number of healthcare professionals retained to provide the services is not greater than the number reasonably necessary to achieve the identified purpose, and (e) the amount of the payments represents fair market value for the services rendered and is not tied to the volume or value of business generated by the healthcare professional on behalf of the member company. In addition, member companies should regularly review their utilization of consultants in order to verify that they have retained the appropriate number of consultants.

5. What are the parameters for determining fair market value?

Fair market value should be determined by acceptable methods that are relevant to determining payments to healthcare professionals. Under no circumstances should the determination of fair market value be impacted by the volume or value of business generated by a healthcare professional on behalf of the member company.

6. May a member company provide pricing discounts to healthcare professionals and their family members who enroll with the member?

Yes, so long as the discounts are reasonable and offered to all healthcare professionals and not a particular specialty or specialties within the healthcare profession (i.e. obstetricians). A discount is not considered reasonable if it is likely to influence the recipient to recommend a member company's products or service to his/her patients or to refer his/her patients to the member company. Providing processing and/or multiple years of storage to a healthcare professional for free would not be considered a reasonable discount.

- 7. May a member company pay a healthcare practitioner to disseminate its marketing materials or literature to his or her patients or to otherwise educate his or her patients on its products or cord blood banking generally in the context of patient consultation?**

No. This restriction does not preclude member companies from paying healthcare professionals under arrangements that would otherwise comply with the codes and this guidance document.

- 8. May a member company pay a healthcare practitioner to listen to an informational presentation on its services and products?**

No. Informational presentations may be accompanied by meals so long as the meals are (a) modest as judged by local standards, and (b) occur in a venue and manner conducive to informational communication. A member company may not pay healthcare professionals to attend an informational presentation or pay their travel or lodging expenses in connection with attending an informational presentation. In addition, entertainment/recreational events may not be offered with or accompany the informational presentation.

- 9. May a member company pay the travel and lodging expenses of a healthcare practitioner to attend meetings at its facilities or otherwise that primarily consist of informational presentations on its services and products?**

No. Informational presentations must meet the standards set forth in #8.

- 10. May a member company train healthcare professionals to serve as speakers on behalf of the member company and its products?**

Yes. Healthcare professionals who participate in speaker training programs may be offered reasonable compensation for their time, considering the value of the type of services provided, and reimbursement for reasonable travel, lodging and meal expenses when (a) the participants receive extensive training on the company's products and on compliance with regulatory requirements for communications about such products, (b) the training will result in the participants providing a valuable service to the company, and (c) the participants meet the criteria for consultants set forth in #4 above.

- 11. May a member company pay or otherwise reward healthcare professionals for providing patient referrals or otherwise recommending the company or its products to patients?**

No.

12. May a member company provide gifts to healthcare practitioners?

On an occasional basis, a member company may offer healthcare practitioners items that are primarily for the benefit of the patient if they are valued (on a retail basis) at \$100 or less. For example, a medical textbook or an anatomical model for use in an examination room involves a patient benefit. A DVD player or VCR does not.

In addition, a member company may offer items of minimal value to healthcare professionals if they are primarily associated with his or her practice (such as pens, notepads and similar reminder items with company or product logos).

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, CDs or tickets to a sporting event) should not be offered.

In addition, payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals, except as compensation for legitimate services or unless the gift certificate can only be redeemed for a gift that meets the requirements set forth above.