



THE AMERICAN NATIONAL RED CROSS
BOARD OF GOVERNORS

QUALITY AND REGULATORY COMPLIANCE SUBCOMMITTEE OF THE
AUDIT AND RISK MANAGEMENT COMMITTEE CHARTER

I. PURPOSE

The Quality and Regulatory Compliance Subcommittee (the "Subcommittee") is appointed by the Audit Committee of the Board of Governors (the "Board") of The American National Red Cross (the "Corporation"). The purpose of the Subcommittee is to assist the Audit and Risk Management Committee (the "Committee") in: (1) overseeing and monitoring compliance with all applicable federal and state laws and regulations related to Biomedical Services, including but not limited to, Food and Drug Administration (the "FDA") regulations and laws and the Amended Consent Decree (the "Consent Decree"); (2) overseeing quality assurance and regulatory compliance with matters related to the American Red Cross Biomedical Services including operations support systems related to compliance; (3) assuring that problems and high risk areas are identified and mitigated to achieve compliance with the Consent Decree, the FDA and other regulatory and legal requirements related to Biomedical Services; (4) reviewing the results and reports of internal and external audits and other compliance assessments related to Biomedical Services and requiring corrective measures for any identified problem areas; (5) recommending additional actions and/or resources, including additional auditing, to ensure compliance with all applicable federal and state laws and regulations, and other legal obligations, related to Biomedical Services including the Consent Decree.

II. COMPOSITION

The Subcommittee shall be composed of at least two but not more than four members of the Board of Governors. All members of the Subcommittee shall be members of the Committee and appointed and subject to removal by the Committee in accordance with the Corporation's Bylaws.

III. AUTHORITY AND RESPONSIBILITIES

In furtherance of the Subcommittee's purpose, the Subcommittee shall have the following authority and responsibilities:

A. Compliance and Oversight Responsibilities

1. Review with management documents provided to the Corporation by the FDA including 483s and management's responses and other federal and state regulatory authorities related to Biomedical Services compliance. All Warning Letters and Adverse Determination Letters from the FDA and similar correspondence shall be supplied to the Committee promptly upon receipt and the Corporation's responses thereto.
2. Assist the Committee in reviewing copies or summaries of reports prepared by third party consultants or auditors retained to evaluate the Corporation's compliance and quality control systems and programs related to Biomedical Services.

3. Assist the Committee in reviewing reports from management summarizing the performance of the Corporation's Biomedical Services quality department and assessing the effectiveness of the Corporation's Biomedical Services quality assurance programs and activities, the results of any internal or external audits of the performance of the Biomedical Services quality department, and reports on any other Biomedical Services regulatory, compliance or quality matters, including efforts to comply with the Consent Decree.

B. Reporting

1. The Subcommittee shall meet with the Committee after each Subcommittee meeting to provide reports and make recommendations to the Committee to address these matters, including but not limited to use of additional resources, oversight, auditing, and investigation activities.

C. Other Authority and Responsibilities

1. Have such other authority and responsibilities as may be provided in the Corporation's Bylaws or may otherwise be delegated to the Subcommittee by the Committee.
2. Perform any other activities consistent with this Charter, the Corporation's Bylaws and applicable law, as the Committee deems necessary or advisable or as required by law or regulation.

The Subcommittee shall keep minutes of all its proceedings; all recommendations of the Subcommittee shall be reported to the Committee at the next Committee meeting.

IV. MEETINGS

The Chair of the Subcommittee in consultation with the Audit Committee, shall determine the schedule and frequency of Subcommittee meetings.

V. QUORUM

A majority of the members of the Subcommittee shall constitute a quorum.

VI. EVALUATION OF COMMITTEE

The Subcommittee shall also recommend to the Committee any modifications of this Charter that the Subcommittee deems necessary or appropriate.