KAISER PERMANENTE

QUALITY ASSURANCE PROGRAM
FOR VENDORS, CONTRACTORS AND SUPPLIERS

Background. Kaiser Foundation Hospitals (KFH) and Kaiser Foundation Health Plan, Inc. (KFHP), including each of their respective subsidiaries, are required to have programs in place to monitor the quality of the goods and services used in their healthcare facilities, including those goods and services supplied by vendors, contractors and suppliers.

KFH and KFHP are collectively referred to as "KFH/HP". Vendors, contractors, and suppliers are referred to as "Supplier".

If requested by KFH/HP, Supplier shall participate in the Quality Assurance Program described below.

1. KFH/HP Oversight. Through its quality assessment and improvement programs, KFH/HP monitors the quality of goods and services provided by Supplier at KFH/HP healthcare facilities as required by applicable local, state and federal laws, rules and regulations. KFH/HP retains administrative and professional responsibility for all services rendered by Supplier at a KFH/HP healthcare facility as required by the California Code of Regulations Title 22 Section 7071 (for CA healthcare facilities), the Code of Federal Regulations Part 42 Section 482.12(e), and other applicable state and federal laws, rules and regulations. KFH/HP also performs quality oversight for the goods and services provided by Supplier at its healthcare facilities as required by The Joint Commission (TJC), NCQA, AAAHC, DNV GL, and CMS. The foregoing does not modify the allocation of liability or indemnification obligations between KFH/HP and Supplier as set forth in contracts between the parties or as otherwise provided by law.

As part of KFH/HP's Quality Oversight, KFH/HP may require Supplier to meet (and provide regular reporting) on certain quality metrics applicable to the goods/services supplied by Supplier, including the following:

a. Supplier shall provide to KFH/HP a quality complaints report, on a monthly basis, that includes details of quality complaints reported to Supplier by KFH/HP employees, clinicians, affiliates, or any other individuals associated with KFH/HP.

b. If Supplier is providing Personal Protective Equipment ("PPE") products to KFH/HP, Supplier must, on an annual basis, provide (i) evidence of PPE process and manufacturing control plan, that correlates to the appropriated regulatory test standards such as ASTM, NIOSH, ANSI, AAMI, 16 CFR, etc., for incoming materials, manufacturing process and final quality; or (ii) the certified laboratory PPE test reports completed within the last 12 months.

2. Cooperation. Supplier agrees to participate in KFH/HP quality assessment and improvement programs (including cooperating with quality improvement activities, providing applicable performance data, and tracking and regular reporting on mutually agreed upon quality indicators), all in accord with KFH/HP's expectations and licensing/accreditation standards. Supplier agrees to abide by KFH/HP quality assessment and improvement plans, and cooperate by objectively monitoring and evaluating the quality of goods and services provided by Supplier to KFH/HP (including, but not limited to, the availability, accessibility, acceptability, and continuity of goods and services).

3. Resolution of Issues. Supplier must (a) investigate and respond immediately to all quality issues and requests for information, and (b) work with KFH/HP to resolve any quality issues related to the goods and services provided by Supplier to KFH/HP. Supplier must remedy, as soon as reasonably possible, any condition that may impact patient care at a KFH/HP healthcare site or that any government or accrediting agency determines to be unsatisfactory. Supplier will work with KFH/HP (a) to continuously assess and improve the quality and accessibility of goods and services provided to KFH/HP, and (b) to resolve problems related to the provision of goods and services.

4. **Site Evaluations**. Supplier must permit periodic site inspections and/or evaluations by KFH/HP, appropriate governmental agencies, and/or independent quality review and improvement organizations.

5. **Medical Device Quality Management**. Manufacturers of medical devices supplied to KFH/HP are expected to have a Quality Management System in place that complies with the requirements of ISO9001, ISO13485, FDA 21 CFR Part 820 and/or other comparable standards or regulations and are expected to have completed FDA registration and device listing requirements per FDA 21 CFR Part 807, as applicable.