

## GS1® HEALTHCARE REQUIREMENTS FOR VENDORS, CONTRACTORS, AND SUPPLIERS

### A. Definitions.

*“Customer”* means a Kaiser Permanente entity purchasing goods or services from Supplier.

*“Kaiser Permanente”* means the integrated health care delivery organization doing business as Kaiser Permanente®, which includes Customer and its affiliates.

*“Product”* means a medical device or product.

*“Supplier”* means a vendor, contractor, or supplier who is providing Products to a Customer.

B. Requirements. Kaiser Permanente supports and is enforcing the implementation of the GS1 Device Identification in the health care industry as the standardized system for marking medical devices and products with a unique device identifier (“UDI”) at all units of use (e.g. box, case, each). Kaiser Permanente also supports an accelerated timeline for the implementation of UDIs using the GS1 Standard in an effort to improve the safety and effectiveness of medical devices.

Kaiser Permanente requires each Supplier of Products to implement the GS1 standard for UDI, label packages and publish to the GDSN as described below:

(i) Access to GTINs and GDSN Certified Data Pool. Supplier must (a) assign a GTIN to identify each Product at all applicable levels of packaging, including the lowest unit of patient use (e.g. case, box, each) and (b) permit Kaiser Permanente to access all product attributes related to the Products using the services of a GS1 Global Data Synchronization Network (“GDSN”) Certified Data Pool Provider; and

(ii) Labeled Inventory. Supplier will only ship Products to Kaiser Permanente labeled in accordance with the FDA UDI Rule at all levels of packaging (e.g. case, box, each) using the GS1 labeling system requirements, including labeling each Product with a GS1-compliant barcode at the lowest unit of patient use.

C. Audit. Supplier is responsible for maintaining readily available documentation, photographs and product packaging that will enable Kaiser Permanente to reasonably audit compliance with these requirements.

D. Failure to Comply. If Supplier fails to provide Kaiser Permanente with compliant GS1-labeled shipped Products at the lowest unit of patient use, then Supplier must reduce the price of each non-compliant Product to Kaiser Permanente by 10% until the Product labeling is compliant with these GS1 Requirements.