



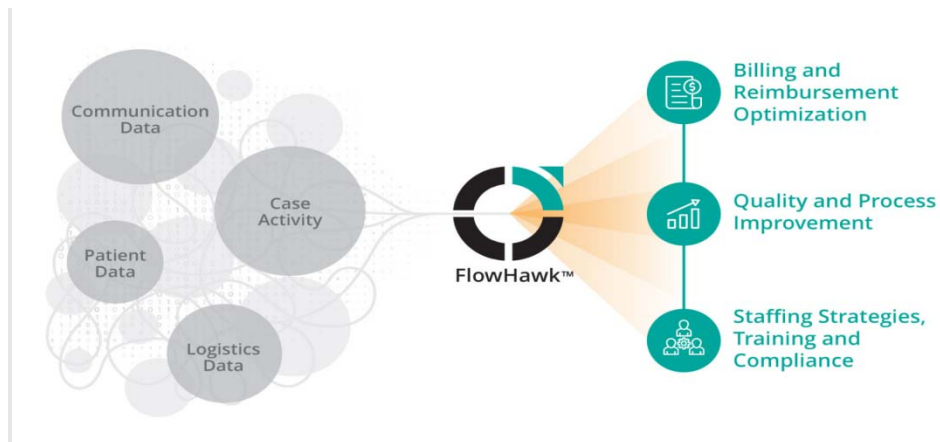
Nov 15, 2022

To whom it may concern,

OmniLife Health offers a HIPAA compliant, clinical workflow automation and communication platform, FlowHawk (tm), that connects care teams and standardizes complex care pathways for organ recovery and organ intake.

FlowHawk provides a single source solution that is easily accessible through a mobile app or desktop for transplant care teams to communicate (verbal, written and print), collaborate and document organ recovery and organ intake case activity, provide data and insights that help improve productivity, mitigate the impact of staffing shortages, and optimize billing. FlowHawk can also be integrated into Electronic Medical Records (EMRs), logistic software, clinical decision support tools and other critical systems.

FlowHawk replaces the manual, fragmented and inefficient process of care teams relying on unsecure, multi-channel communications tools (phone calls, fax, email and text messaging) for organ procurement and transplant.



OmniLife Health requested that Guidry & East review existing Medicare regulation concerning the use of FlowHawk and the related reimbursement for the purchase of FlowHawk based on the Medicare cost report. Based on our research of existing CMS rulings and review of regulation, it is our opinion that the costs associated with the use of the OmniLife communication solution must be reasonable, related to donor and transplant patient care, not a duplication of an existing product offered by the OPOs or Transplant hospitals and is not to be used for advertising purposes (e.g., cross-selling for other OPO or hospital services.)

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The following definitions relate to the expense for it to be allowable on the Medicare cost report:

- (1) **Provider Reimbursement Manual, Section 2102.1 – Reasonable Costs:** The costs ... should not "exceed what a prudent and cost-conscious buyer pays for a given item or service."

Reasonable costs of any services are determined in accordance with regulations establishing the method or methods to be used, and the items to be included. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs. The objective is that under the methods of determining costs, the costs for individuals covered by the program are not borne by others not so covered and the costs for individuals not so covered are not borne by the program.

Costs may vary from one institution to another because of scope of services, level of care, geographical location, and utilization. It is the intent of the program that providers are reimbursed the actual costs of providing high quality care, regardless of how widely they may vary from provider to provider, except where a particular institution's costs are found to be substantially out of line with other institutions in the same area which are similar in size, scope of services, utilization, and other relevant factors. Utilization, for this purpose, refers not to the provider's occupancy rate but rather to the manner in which the institution is used as determined by the characteristics of the patients treated (i.e., its patient mix, age of patients, type of illness, etc.).

Implicit in the intention that actual costs be paid to the extent they are reasonable is the expectation that the provider seeks to minimize its costs and that its actual costs do not exceed what a prudent and cost-conscious buyer pays for a given item or service. (See §2103). If costs are determined to exceed the level that such buyers incur, in the absence of clear evidence that the higher costs were unavoidable, the excess costs are not reimbursable under the program.

- (2) **Provider Reimbursement Manual, §2102.2 – Costs Related to Patient Care:** The costs must be necessary and proper costs which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. Necessary and proper costs related to patient care are usually costs which are common and accepted occurrences in the field of the provider's activity. They include personnel costs, administrative costs, costs of employee pension plans, normal standby costs, and others. Allowability of costs is subject to the regulations prescribing the treatment of specific items under the Medicare program.
- (3) **Provider Reimbursement Manual, §2136.1 –** Costs of activities involving professional contacts with physicians, hospitals, public health agencies, nurses' associations, State and county medical societies, and similar groups and institutions, to apprise them of the availability of the provider's covered services are allowable. Such contacts make known what facilities are available to persons who require such information in providing for patient care, and serve other purposes related to patient care, e.g., exchange of medical information on patients in the provider's facility, administrative and medical policy, utilization review, etc. Similarly, reasonable production and distribution costs of informational materials to professional groups and associations, such as those listed above, are allowable if the materials primarily refer to the provider's operations or contain data on the number and types of patients served. Such materials should contribute to an understanding of the role and function of the facility as a provider of covered health care in the community.
- (4) **Provider Reimbursement Manual, §2136.2 – Advertising Costs:** When developing flyers/videos/training for dialysis patients, the material and instruction should not contain information about the provider that "seeks to increase patient utilization of the provider's facilities" which is considered to be non-allowable for cost reimbursement.

- Costs of fund-raising, including advertising, promotional, or publicity costs incurred for such a purpose, are not allowable.
- Costs of advertising of a general nature designed to invite physicians to utilize a provider's facilities in their capacity as independent practitioners are not allowable. (See §2136.1 for allowability of professional contact costs and costs of advertising for the purpose of recruiting physicians as members of the provider's salaried staff.)
- Costs of advertising incurred in connection with the issuance of a provider's own stock, or the sale of stock held by the provider in another corporation, are considered as reductions in the proceeds from the sale and, therefore, are not allowable.
- Costs of advertising to the general public, which seeks to increase patient utilization of the provider's facilities are not allowable. Situations may occur where advertising which appears to be in the nature of the provider's public relations activity is, in fact, an effort to attract more patients. An analysis by the intermediary of the advertising copy and its distribution may then be necessary to determine the specific objective. While it is the policy of the Health Care Financing Administration and other Federal agencies to promote the growth and expansion of needed provider facilities, general advertising to promote an increase in the patient utilization of services is not properly related to the care of patients.

Based on our review of the regulations and the above discussion, we believe that the costs associated with:

- The use of the OmniLife Health FlowHawk platform and related costs appear to be allowable costs on the OPO Medicare cost report (for kidney donor use) and appear to be allowable costs on the Transplant Hospital Medicare cost report per CMS approved organ type. Based on our research of existing CMS rulings and review of regulation, it is our opinion that the costs associated with the use of the OmniLife Health FlowHawk platform are reasonable, related to donor and transplant patient care, represent a safer, more efficient and compliant mode of communication offered to OPOs and Transplant hospitals and is not intended to be used for advertising purposes (e.g., cross-selling for other OPO or hospital services.)
- The OPO and transplant educational materials developed to deploy the OmniLife Health FlowHawk platform , as long as they are available to donor families, and any patient or dialysis center in a service area, are allowable costs on the Medicare cost report. The contact information for the OPO and the Transplant Center may be printed on these educational materials.
- Individual or group trainings to deploy the OmniLife Health FlowHawk platform are allowable costs for inclusion on the Medicare cost report as long as the educational activities pertain to kidney organ donors and patient treatment options, including organ transplant. Such educational activities are a necessary and proper cost.

Guidry & East, LLC is a Healthcare Consulting firm specializing in the field of Solid Organ Procurement and Transplantation. We have had the pleasure of working with a large number of organ banks and transplant centers in the United States since 1986. We are experienced in all regulatory issues concerning solid organ recovery and transplantation.

Among the services we provide, are:

- Transplant Center Financial & Operational Assessments
- Organ Procurement Organization (OPO) Financial & Operational Assessments
- Financial Audit & Clinical Analysis of the Medicare Organ Acquisition Cost Report

- Medicare Organ Acquisition Cost Report Review Before Filing
- Transplant Regulatory Compliance Reviews
- Transplant Center Business Development/Financial Pro Forma
- Transplant Center and OPO Operational Support:
 - Onsite Consultants
 - Independent Peer Review Teams

Guidry & East would be glad to speak to any OPO or transplant center interested in OmniLife Health FlowHawk platform - related expenses on their Medicare OPO and Transplant Center cost reports and answer any questions about this matter.

Respectfully,

A handwritten signature in blue ink, appearing to read "B. Aussi", with a long horizontal stroke extending to the left.

B. Alexander Aussi, BSN, RN, MBA
Chief Executive Officer