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# Standards of Practice

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## Standards for Specialized Nutrition Support: Home Care Patients

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The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is a professional society of physicians, nurses, dietitians, pharmacists, allied health professionals, and researchers dedicated to assuring that every patient receives optimal nutrition care. A.S.P.E.N.'s mission is to serve as the preeminent, interdisciplinary nutrition society dedicated to patient-centered, clinical practice worldwide through advocacy, education, and research in the field of specialized nutrition support. These Standards for Specialized Nutrition Support: Home Care Patients are an update of the 1999 standards. These standards present a range of performance of competent care based on expert clinical opinion that should be subscribed to by any home care provider caring for patients receiving home enteral or parenteral nutrition. A separate reference, "Guidelines for the Use of Parenteral and Enteral Nutrition in Adults and Pediatric Patients,"<sup>1</sup> provides evidence-based practice guidelines that are coded to reflect the strength of evidence supporting the guideline to assist clinicians in their decision-making process in the development of nutrition care plans (NCP) for patients.

Use of the word *shall* within this document indicates standards to be followed strictly to conform to the standard; use of *should* indicates that among several possibilities, one is particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required. *May* is used to indicate a course of action that is permissible within the limits of recom-

mended practice. A list of definitions is included in the last chapter of this standard to assist the reader in understanding terms used in this standard.

The standards are presented in the most generic terms possible. The details of specific tests, therapies, and protocols are left to the discretion of individual home care providers. Each home care provider shall strive to provide the best nutrition support structure that is possible, given the resources of the organization. The standards aim to assure sound and efficient nutrition education and care for those patients in need of home enteral or PN.

These standards do not constitute medical or other professional advice and should not be taken as such. To the extent that the information published herein may be used to assist in the care of patients, this is the result of the sole professional judgment of the attending healthcare professional whose judgment is the primary component of quality medical care. The information presented in these standards is not a substitute for the exercise of such judgment by the healthcare professional. These standards have been developed, reviewed, and approved by the A.S.P.E.N. Standards Committee and the A.S.P.E.N. Board of Directors.

### CHAPTER I: Organization

#### Standard 1. Nutrition Support Services

Interdisciplinary nutrition care planning shall be achieved through collaboration of the referring physician, home care provider, and nutrition support practitioner(s).

- 1.1. The role of each healthcare professional is clearly defined and responsibilities are designated.<sup>2-5</sup>
- 1.2. The physician who has expertise in home parenteral nutrition (PN) and enteral nutrition (EN) support or a physician who works with a multidisciplinary team primarily

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should be responsible for the patient's nutrition care. The physician should act in collaboration with a nurse,\* dietitian,\* pharmacist,\* and other healthcare professionals as needed. Each healthcare professional shall demonstrate competency in nutrition support.<sup>2-5</sup>

- 1.3. Home PN and EN support shall be initiated, modified, supervised, evaluated, and coordinated by the referring physician, home care provider, and nutrition support practitioner(s).

\*Use of the titles *nurse*, *dietitian*, and *pharmacist* refers to registered nurse, registered dietitian, and registered pharmacist.

### Standard 2. Policies and Procedures

The referring physician, home care provider, and nutrition support practitioner(s) managing care for a patient receiving home PN and EN shall be guided by policies, procedures, and other written processes.

- 2.1. Policies and procedures shall be appropriately developed, reviewed, revised, and dated to reflect optimal standards of care.
- 2.2. There shall be written policies and procedures concerning the scope and provision of home PN and EN services, which shall include, but not be limited to the following:
  - 2.2.1. The qualifications, roles, and responsibilities of the referring physician, home care provider, and nutrition support practitioner(s).
  - 2.2.2. Ongoing competency assessment program for staff members.
  - 2.2.3. Individuals authorized to prescribe home PN and EN therapies.
  - 2.2.4. Criteria for patient eligibility and selection, including medical suitability, rehabilitative potential, home environment evaluation, social and economic constraints, educational abilities, and psychosocial factors.
  - 2.2.5. A process for referral to a home care provider for provision of parenteral or enteral formulations, equipment, supplies, and nursing care.
  - 2.2.6. Education, training, and evaluation of patient/caregiver competency.
  - 2.2.7. A process for patient monitoring (eg, frequency of follow-up, nutrition assessment, laboratory studies, response to nutrition therapy, and physical examination).
  - 2.2.8. A process for referral to consultative medical services, psychologists, social workers, community resources, and patient support groups, as appropriate.
  - 2.2.9. Reimbursement processes for payment of services, equipment, and supplies.
  - 2.2.10. Preparation, storage of, and techniques

for administering PN or EN therapy in the home.

- 2.2.11. Equipment and maintenance tracking system.
- 2.2.12. Disposal of medical equipment and supplies.
- 2.2.13. Prevention, management, and timely response to complications in the home.
- 2.2.14. Emergency preparedness plan for the home care provider, and for patients and caregivers.
- 2.2.15. A process for timely communication and collaboration among the referring physician, home care provider, nutrition support practitioner(s), patient, caregiver, and other healthcare professionals involved.
- 2.2.16. Discharge-from-service criteria for termination of services.

### Standard 3. Access to Care

The patient/caregiver and all healthcare professionals involved in the care of the patient shall have access to a home care provider that provides 24-hour on-call services.

### Standard 4. Medical Record

The home care provider shall initiate and maintain a medical record for every patient receiving home PN or EN.

- 4.1. Confidentiality, sensitivity, and integrity of data and information will be maintained in compliance with the Health Insurance Portability and Accountability Act.
  - 4.1.1. Names and contact information of caregivers who will assist in care of the patient should be documented.
- 4.2. Medical records shall include, but not be limited to, documentation of the following:
  - 4.2.1. Consent for care.
  - 4.2.2. A treatment plan signed by the physician including prescriptions for PN or EN therapies, medications, and orders for activity level, access-site care, and oral diet.
  - 4.2.3. Contact information for the physician or other nutrition support practitioners shall be documented.
  - 4.2.4. Functional status of the patient, permitted activities, psychosocial needs, suitability of home environment for nutrition therapy.
  - 4.2.5. All pertinent patient diagnoses, prognosis, and short-term and long-term treatment objectives, and estimated duration of therapy.
  - 4.2.6. Results of nutrition assessment and findings on physical examination.
  - 4.2.7. Education and training of patient

and/or caregivers, including competency evaluation.

- 4.2.8. A current medication profile, including prescription and nonprescription drugs, vitamin/mineral supplements, oral nutrition or herbal supplements, home remedies, known drug allergies or sensitivities, and history of tobacco use, alcohol, and illicit drug use.
- 4.2.9. Signed and dated progress notes for each contact between the home care provider and the patient, referring physician or nutrition support practitioner(s). Progress notes shall include significant changes to therapy or complications including the goals of therapy, and shall report response to nutrition therapy including but not limited to results of serial monitoring, revisions in the NCP, and patient compliance with procedures and techniques.
- 4.2.10. Documentation at termination of nutrition therapy should include but not be limited to the following: reason for terminating treatment, attainment of care plan goals, complications, patient outcome, and follow-up.

#### **Standard 5. Performance Improvement**

Nutrition support is a high-risk, problem-prone treatment and shall be addressed in the home care provider's performance improvement and outcome measurement activities.

- 5.1. Data to be collected shall include but not be limited to mortality, hospital readmission, complications, customer satisfaction, and problem-reporting and resolution.
- 5.2. Outcomes shall be assessed in relation to internal or national benchmarks.
- 5.3. Sentinel events (rare but serious adverse outcomes) related to treatment shall be appropriately assessed and reported to appropriate regulatory agencies.

## **CHAPTER II: Nutrition Care Process**

#### **Standard 6. Nutrition Screening**

Criteria shall be established for identification of patients who are nutritionally-at-risk by an initial screening mechanism.<sup>6-8</sup>

- 6.1. All patients admitted to the home care provider shall undergo nutrition screening using subjective and/or objective criteria within 72 hours of acceptance or on the initial home visit.<sup>9</sup>
- 6.2. The policy, procedure, and content of the nutrition screen shall be formalized and documented.
- 6.3. The result of the nutrition screen shall be documented.
- 6.4. Patients identified on initial screen as nutri-

tionally-at-risk shall be referred to the physician for further orders regarding nutrition assessment and intervention.

- 6.5. Patients identified as not nutritionally-at-risk shall be rescreened at regularly specified intervals or when their clinical or nutrition status changes.

#### **Standard 7. Nutrition Assessment**

All patients identified as nutritionally-at-risk by the patient screening mechanism or requiring home PN or EN shall have a nutrition assessment. The results of the nutrition assessment and recommendations should be shared with all patient care providers.

- 7.1. The nutrition assessment shall be performed by, or under the supervision of, a registered dietitian or healthcare professional with training and expertise in PN and EN within a time frame specified by organizational policy.
- 7.2. Subjective and objective assessment of the patient's current nutrition status and requirements shall occur.<sup>10</sup>

7.2.1. The subjective assessment of nutrition status should include a nutritionally focused history. Elements that should be documented as part of the subjective assessment include the following: recent changes in dietary intake (quantitative and qualitative); mastication, swallowing, gastrointestinal and elimination symptoms (including stomatitis, nausea, vomiting, diarrhea, constipation, and anorexia); functional and anatomic status of gastrointestinal tract, current status and recent changes in functional capacities (eg, ambulation, employment, recreation, endurance, mental status); psychosocial factors (eg, social support; eating disorders; language barriers; family dynamics; personal, ethnic, cultural, or religious dietary prescriptions; substance abuse; psychiatric disorders); socioeconomic factors (eg, personal financial situation); patient preferences and directives with regard to intensity and invasiveness of care; emotional response to current illness; admitting diagnosis; concurrent medical and surgical problems that may affect nutrition requirements; and nutrition support options, including medications, allergies (food, drug, or latex), and home remedies.

7.2.2. The objective assessment of nutrition status should include data obtained from the physical examination, anthropometric measurements, and laboratory data. Elements of the physical examination relevant to nutrition status should include loss of subcutaneous fat, muscle

wasting, presence of edema, ascites, mucocutaneous lesions, hair and skin changes, presence of wounds, and patient specific indices as determined from the subjective portion of the nutrition assessment.

Anthropometric data that shall be documented include height, length, head circumference (if applicable), altered height and weight relationship, current body weight, ideal body weight, usual body weight; recent change in weight (quantified), and body mass index.

Laboratory data<sup>9</sup> that should be reviewed and documented may include complete blood count with differential; serum electrolytes (including calcium, phosphorous, and magnesium), blood urea nitrogen, and creatinine; glucose; albumin; aspartate aminotransferase; alkaline phosphatase; total bilirubin; prothrombin time; international normalized ratio; and triglycerides.

- 7.3. If home PN or EN is indicated, the patient's home environment, medical suitability, rehabilitative potential, educational level or learning ability, and reimbursement sources shall be assessed by the physician, case manager, and/or other designated healthcare professionals to determine the availability of appropriate resources prior to initiation.
  - 7.3.1. The patient's home shall be determined appropriate for the administration of home PN or EN support; eg, the patient should have a clean environment, sanitary water supply, electricity, refrigeration, adequate storage space for supplies, and access to a telephone.
  - 7.3.2. The patient/caregiver shall be willing and able to perform home PN and EN therapy and associated procedures.
  - 7.3.3. The patient/caregiver shall be able to troubleshoot minor problems or call for assistance when complications occur.
  - 7.3.4. The patient/caregiver shall be informed and knowledgeable about the rationale, therapeutic goals and options, risks, benefits, and responsibilities (financial and otherwise) of home PN and EN and agree to participate.
- 7.4. Initiation of PN in the home setting shall only be considered in patients who are clinically stable, have an appropriate indication for PN, are able to be evaluated in the home, and are capable of being educated in the safe administration of the therapy. Initiating therapy at home shall be considered only when assessment confirms that the benefits greatly outweigh the risks.
  - 7.4.1. Review of patient's medical and social

history, age, laboratory data, and indication for PN shall occur.

- 7.4.2. Laboratory data shall be obtained within 48 hours prior to initiation of home PN.<sup>9</sup> More frequent assessment of laboratory data may be required to ensure efficacy and prevent complications of nutrition support when initiated in the home. Laboratory data may need to be modified for pediatric patients.
- 7.4.3. High-risk patients who may not be candidates for the initiation of PN in the home setting include patients at risk for the refeeding syndrome; infants; IV drug abusers; and patients with diabetes, fluid and electrolyte/acid-base disorders, and major organ dysfunction. Patients with these conditions may need more frequent monitoring and clinical assessment than can be managed at home.
- 7.4.4. Once therapy is initiated, the patient/caregiver must be able to: recognize vascular access device (VAD) complications, including signs and symptoms of catheter-related infection; recognize signs and symptoms of fluid imbalance; perform fingerstick glucose or urine testing for glycosuria; recognize signs and symptoms of hyperglycemia or hypoglycemia; and troubleshoot pump malfunction or problems.
- 7.5. The results of the nutrition assessment shall be summarized and documented.
  - 7.5.1. A classification system for nutrition risk according to the findings of the subjective and objective nutrition assessments shall be used.
  - 7.5.2. Patient's nutrition requirements shall be summarized according to the findings of the subjective and objective nutrition assessments. The summary should include appropriate route of administration, fluid, protein and calorie requirements. The summary should also include electrolyte and micronutrient requirements.
- 7.6. Patients who are not considered candidates for home PN or EN shall be provided with alternative choices/settings for receiving nutrition support.

## CHAPTER III: Development of NCP

### Standard 8. Interdisciplinary Approach

The NCP shall be developed with an interdisciplinary approach involving the patient, the patient's referring physician, home care provider, and other healthcare professionals involved in the care of the patient as appropriate.

**Standard 9. Objectives**

The objective(s) of nutrition care shall be determined and documented. This should include immediate and long-term goals of nutrition therapy, anticipated duration of therapy, and patient education.

**Standard 10. Goals and Expectations**

The NCP shall address patient and family caregiver education about nutrition support therapy and involvement in decisions regarding goals of treatment.

10.1. The NCP shall include nutrition goals; route for administration; prescribed nutrients; infusion schedule; drug-nutrient interactions; specialized techniques of preparation and administration in the home setting; care of access device, equipment, solutions, and formulas; monitoring frequency; and a plan to implement if problems related to infusion access devices, equipment, or patient symptoms develop.

**CHAPTER IV: Implementation and Education****Standard 11. Ordering Process**

Implementation should commence after assessment and development of an NCP.

- 11.1. Implementation of an NCP shall have a defined ordering process.
- 11.2. Verbal prescriptions/orders for PN or EN therapy shall be accepted only by personnel designated by the home care provider and authenticated by the prescribing/ordering practitioner within a defined time period or as required under applicable law and/or regulations. All verbal prescriptions or orders should be read back to the prescribing/ordering practitioner.
- 11.3. Prescriptions/orders for PN or EN therapy shall be maintained in the patient's medical record or received as required by law and regulation before any therapy is administered.

**Standard 12. Nutrition Support Access**

The route selected to provide nutrition support shall be appropriate to the patient's medical problems, safety, efficacy, and patient preference.

- 12.1. When functional, the gastrointestinal tract is the preferred route for nutrition support and should be used to administer nutrition support.
- 12.2. PN should be provided only when the gastrointestinal tract is nonfunctional, cannot be accessed, or when oral nutrition or EN would exacerbate gastrointestinal tract dysfunction.<sup>1</sup>
- 12.3. Peripheral PN may be given through a peripheral-midline VAD and may be considered to provide nutrition support until central access is obtained.
- 12.4. Access shall be established by a healthcare pro-

fessional who is skilled and competent with the insertion of the device in accordance with state law and regulation.

- 12.5. Confirmation of VAD tip or enteral tube placement is obtained and documented in the patient's medical record prior to administration of therapy.
  - 12.5.1. Central venous access shall be used for administration of central PN. The catheter tip should be positioned in the superior vena cava or adjacent to the right atrium.<sup>1,11</sup>
- 12.6. Standard techniques and protocols shall be established for the proper care and management of the vascular and enteral access.<sup>11,12</sup>

**Standard 13. PN Formulation Selection and Preparation**

PN formulations shall be prepared as prescribed, appropriate for the patient's disease process and compatible with route of access.

- 13.1. PN formulations shall be appropriate for the route of access.
- 13.2. PN formulations shall be adjusted as appropriate in patients with organ dysfunction.
- 13.3. PN formulations should be adjusted when significant amounts of nutrients are provided through means other than PN (eg, oral intake, IV fluids, medications using a lipid-based vehicle, peritoneal dialysis).
- 13.4. PN formulations shall be prepared using policies and procedures governing aseptic technique, manufacturing, compatibility, and stability.<sup>13,14</sup>
- 13.5. Automated compounding devices are recommended for the compounding of PN formulations. Personnel using automated compounding devices shall be trained and demonstrate competency. Training should include education on operation, aseptic technique, appropriate sequencing of additives, periodic calibration, troubleshooting, and maintenance of the device. Procedures shall be developed and followed to assure the quality of the preparation process to minimize the risk of contamination, especially by microorganisms.
  - 13.5.1. PN formulations compounded by an automated compounding device shall be checked against the programmed admixture and weight of components.
  - 13.5.2. The operator shall continuously monitor the automated compounding device during the preparation process to assure proper operation.
  - 13.5.3. Demonstration of competency to safely operate the automated compounding device shall be assessed annually.
- 13.6. PN formulations shall be compounded under sterile conditions and shall comply with national standards.<sup>14,15</sup>

- 13.6.1. Aseptic technique shall be taught, used, and evaluated on a periodic basis.
- 13.6.2. PN admixtures shall be prepared in a class 100 laminar airflow hood using aseptic technique<sup>14,15</sup> and under the direction of a pharmacist.<sup>16</sup>
- 13.6.3. The compounding room should be a controlled room with limited access to decrease the potential for contamination of sterile compounded products.
- 13.7. The final PN formulation shall be checked visually to assure appropriate volume, absence of particulate matter or phase separation in the IV fat emulsion (IVFE).<sup>13</sup>
- 13.8. All PN formulations shall be prepared in compatible containers and shall be administered through a filter. A 0.22- $\mu$ m filter shall be used for 2-in-1 formulations. A 1.2- $\mu$ m filter shall be used for total nutrient admixtures (TNAs). Alternatively, a 1.2- $\mu$ m filter may be used for all PN formulations.<sup>13</sup>
- 13.9. Methods should be taken to limit the amount of aluminum contamination in PN formulations.<sup>17,18</sup>

#### **Standard 14. Packaging and Labeling PN Formulations**

PN formulations shall be visually inspected during preparation, prior to hanging, and during administration to identify potential incompatibilities of the formulation (ie, calcium/phosphate precipitation). PN formulations shall be labeled appropriately, including administration date and time and beyond-use date, in compliance with the A.S.P.E.N. Safe Practices Task Force for Parenteral Nutrition<sup>13,14</sup> and any applicable state regulations. Labeling shall also include any special patient instructions (ie, additives, activation of dual chamber bags, and cycling schedule).

#### **Standard 15. Additives to PN Formulations**

Additives to PN formulations shall be appropriate and compatible with all ingredients.

- 15.1. All patients receiving PN should receive daily parenteral multivitamins in quantities established by the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research.<sup>19,20</sup>
- 15.2. All additions to a PN formulation such as multivitamins shall be made by the patient or caregiver in a designated clean area as instructed by the home care provider. Parenteral multivitamins should be added immediately before starting the PN infusion.
- 15.3. If parenteral iron is clinically indicated, it may be administered as various forms of IV iron. Only iron dextran can be added to a bag that does not contain IVFE. An iron dextran test dose is required before the initial infusion. The

other choices for iron replacement require a separate infusion.

- 15.4. Any additions to a PN formulation by the patient or caregiver shall be approved by the home care provider.
- 15.5. The addition of concentrated electrolytes to PN formulations in the home setting should be avoided.<sup>21</sup>
- 15.6. Addition of electrolytes and medications to a PN formulation after administration has begun shall be avoided.
- 15.7. Healthcare professionals responsible for the preparation and delivery of PN formulations shall use methods for detection or prevention of formulation incompatibilities.
- 15.8. All patients receiving PN should receive daily parenteral trace elements. Dosing may need to be adjusted for severe renal and hepatic dysfunction, excessive losses, or in patients receiving long-term PN.<sup>1</sup>
- 15.9. The addition of calcium and phosphate to PN formulations should comply with guidelines<sup>13</sup> in the literature and manufacturer's guidelines for automated compounding.
- 15.10. Use of calcium chloride shall be avoided due to greater risk of electrolyte and nutrient incompatibility. Calcium gluconate salt is the preferred choice when compounding PN formulations.
  - 15.10.1. Calcium and phosphate salts should not be added in close sequence or consecutively to the PN formulation.
  - 15.10.2. Phosphate should be added prior to the addition of calcium during the compounding process.
  - 15.10.3. Some amino acid formulations contain phosphorus and must be accounted for in the calculation of calcium/phosphorus solubility.
- 15.11. Any additive lacking compatibility and stability data in standard reference sources should not be added to PN formulations.

#### **Standard 16. EN Formulation Selection and Preparation**

EN formulations shall be prepared as prescribed, appropriate for the patient's disease process and compatible with route of access.

- 16.1. EN formulations shall be prepared to prevent contamination. Commercially available EN formulations shall be used whenever possible.
- 16.2. EN formulations shall be prepared by the patient/caregiver who has been trained in accordance with policies and procedures and manufacturer's instructions.
- 16.3. EN formulation preparation equipment shall be routinely sanitized.

**Standard 17. EN Formulation Packaging and Labeling**

EN formulations shall be appropriately packaged and labeled.

- 17.1. EN formulations shall be packaged in containers that can assure cleanliness during preparation, storage, and administration.
- 17.2. EN formulations shall be packaged in containers that assure cleanliness and accuracy of administration.

**Standard 18. Additives to EN Formulations**

Additives to EN formulations shall be safe, stable, and compatible with all ingredients.

- 18.1. Healthcare professionals responsible for the preparation and administration of EN formulations shall have resources available to document compatibility and stability of any additives.
  - 18.1.1. Compatible medications should be administered individually in a manner to avoid tube occlusion and to attain desired therapeutic response. The tube should be flushed after administration of any medication.
  - 18.1.2. Modular nutrition components can be added to EN formulas to increase calories, protein, or fiber as deemed appropriate by the patient's healthcare provider. They should be diluted as necessary to prevent occlusion of feeding apparatus.
- 18.2. Colorants (food coloring or methylene blue dye) should not be added to EN formulations.<sup>22,23</sup>

**Standard 19. Storage and Administration of PN and EN Formulations**

PN and EN formulations shall be stored and administered accurately in accordance with the prescribed therapeutic plan and consistent with the patient's tolerance.

- 19.1. PN formulations should be stored under refrigerated conditions (35.6°F–46.4°F) and warmed to room temperature prior to infusion.<sup>13,14</sup>
- 19.2. Temperature control during transport of sterile products for home use shall be maintained to ensure the stability and integrity of the products in accordance with manufacturer's recommendations or currently accepted standards.
- 19.3. Unopened and partially used commercially available EN products should be stored at temperatures as recommended by the manufacturer.
- 19.4. The use of home prepared or blenderized EN formulations requires additional attention to nutrient content and safe food handling and storage practices. They should be stored under refrigeration and discarded after 48 hours.<sup>24</sup>

19.5. Protocols shall be written regarding techniques used to administer EN and PN formulations.

- 19.5.1. Protocols shall be written to prevent enteral feeding tube or VAD occlusion.
- 19.5.2. A protocol shall be written to prevent infection due to the feeding formulation and the equipment used in its administration.
- 19.5.3. A protocol shall be written regarding the appropriate hang time for PN and EN formulations.<sup>25,26</sup>
  - 19.5.3.1. Once started, the infusion of a PN formulation shall be completed within 24 hours or the remaining formulation shall be discarded.<sup>11</sup>
  - 19.5.3.2. Infusion of IVFE as a separate infusion should be completed within 12 hours or discarded.<sup>25</sup>
- 19.5.4. A protocol should be written to prevent the inadvertent administration of an EN formulation through a VAD.<sup>27</sup>
- 19.6. The nutrient infusion method and infusion control device selected for administration of PN or EN shall be suitable for home use.
- 19.7. Selection of the nutrient infusion method or infusion control device should be based on clinical need, safety, accuracy of delivery, and cost-effectiveness.
- 19.8. Consideration should be given to patient preference, volume to be infused, type of regimen (cyclic, continuous, or intermittent), activity level of the patient, reimbursement issues, and ability/education level.
- 19.9. PN formulations shall be infused using a pump.

**Standard 20. Patient/Caregiver Education on Home PN Administration**

The patient/caregiver shall receive education by qualified members of the healthcare team and demonstrate competence in the preparation and administration of home PN. The education and training are specific to the patient's assessed needs, abilities, and readiness, as appropriate to the care and service provided. This competency and compliance is periodically assessed and documented.

- 20.1. The patient receiving home PN or caregiver should be instructed on the safe and effective use of PN formulations in accordance with legal requirements, including the following:
  - 20.1.1. Name and telephone numbers of resources available 24-hours-a-day to troubleshoot and answer questions.
  - 20.1.2. The name, composition, intended use, and expected outcome of the formulation.
  - 20.1.3. Medication information and adminis-

- tration, including dosage, route, frequency, and the potential for adverse effects and drug interactions.
- 20.1.4. Inspection of home PN containers to assure that the PN bag is intact and there are no leaks.
  - 20.1.5. Inspection of the contents before and after any additives are added to assure there are no precipitates, changes in color, or any disruption/destabilization in the TNA.
  - 20.1.6. Instruction on the safe addition of any additives, including mixing and inspection of the final PN formulations. Importance of not adding any medications not prescribed to the PN to prevent nutrient-drug interactions.
  - 20.1.7. The route of administration and duration of nutrition therapy.
  - 20.1.8. Proper VAD and site care.
  - 20.1.9. Inspection of label prior to administration to ensure the prescribed PN formulation is given to the appropriate patient.
  - 20.1.10. Connecting and disconnecting the IV tubing to the VAD.
  - 20.1.11. Pre- and/or postinfusion flushing to maintain VAD patency and prevent drug-nutrient incompatibility.
  - 20.1.12. Infection control and prevention, including aseptic technique required for any admixture procedures and administration via access device, appropriate handwashing techniques, and standard precautions.
  - 20.1.13. Verification of proper pump programming each time a new volume of PN is ordered.
  - 20.1.14. Compatibility and stability of PN and coadministered solutions under refrigeration or at room temperature.
  - 20.1.15. Techniques for self-monitoring and identification of potential complications of therapy.
  - 20.1.16. Proper storage of the PN bag and identification of the "do not use after" or "beyond use" date on the label of the PN bag.
  - 20.1.17. Use and storage of infusion pump and supplies, including safety, cleaning, disinfecting, emergency backup, and troubleshooting.
  - 20.1.18. Proper disposal of used containers, tubing, needles, and unused or outdated PN and/or medications.
  - 20.1.19. Action to be taken in the event of late or missed administration of PN.
  - 20.1.20. Process to order additional PN, patient additives, or supplies.

- 20.1.21. Basic home safety (fire, electrical, environment, mobility, bathroom).
- 20.1.22. Information on emergency preparedness to assist patients and caregivers if an emergency should interrupt service.

#### **Standard 21. Patient/Caregiver Education on Home EN Administration**

The patient/caregiver shall receive education by qualified members of the healthcare team and demonstrate competence in the preparation and administration of home EN. The education and training are specific to the patient's assessed needs, abilities, and readiness, as appropriate to the care and service provided. This competency and compliance is periodically assessed and documented.

The patient receiving home PN or caregiver should be instructed on the safe and effective use of PN formulations in accordance with legal requirements, including the following:

- 21.1. The name, composition, intended use, and expected outcome from the formulation.
- 21.2. Medication information and administration, including dosage, route, frequency, and the potential for adverse effects and drug interactions.
- 21.3. Timing, method of administration, and feeding schedule.
- 21.4. The route of administration and duration of nutrition therapy.
- 21.5. Care of the enteral access device.
- 21.6. Product hang time and stability at room temperature.
- 21.7. Inspection of enteral products for contents and expiration date.
- 21.8. Clean technique for preparation of EN, administration, and reuse of supplies and equipment.
- 21.9. Techniques for self-monitoring of therapy and identification of potential complications.
- 21.10. Proper storage of ready-to-use formula and feeding formulations that require mixing.
- 21.11. Use and storage of enteral feeding equipment and supplies (including safety, cleaning, disinfecting, emergency backup, and troubleshooting).
- 21.12. Proper disposal of used containers, tubing, and unused and/or expired feeding formulations or medications.
- 21.13. Action to be taken in the event of late or missed administration of EN.
- 21.14. Process to order additional feeding formulation and supplies.
- 21.15. Infection prevention and control, ie, standard precautions.
- 21.16. Basic home safety (fire, electrical, environment, mobility, bathroom).
- 21.17. Information on emergency preparedness to assist patients and caregivers if an emergency should interrupt service.

## CHAPTER V: Patient Monitoring

### Standard 22. Parameters and Frequency

Patient monitoring shall be designed to determine the effectiveness and appropriateness of nutrition support. The process of patient monitoring must assure that the nutrition goals are achieved. The monitoring process is also intended to reduce the risk of complications due to nutrition support. Each patient's nutrition status is monitored and documented on a regular basis.

- 22.1. The referring physician, home care provider, and nutrition support practitioner(s) should monitor the clinical status and response to nutrition therapy. This shall include but not be limited to the following:
- Observation for signs and symptoms of intolerance to therapy
  - Evaluation of weight changes and/or growth rates as appropriate
  - Evaluation of hydration status
  - Review of systems and/or physical examination
  - Periodic review of biochemical and/or other pertinent laboratory data
  - Assessment for clinical signs of nutrient deficiencies or excesses
  - Assessment of other disease states or conditions that may affect the nutrition therapy
  - Review for evidence of an interaction between the nutrition therapy and medications or other disease states
  - Evaluation of functional status and performance
  - Inspection of access device and site
  - Patient compliance with techniques and procedures of the nutrition therapy and inventory of formulations
- 22.2. Review the appropriateness of the nutrition therapy, therapeutic regimen, and route of administration. This shall include but not be limited to:
- Assessment of the impact of the current medication regimen on the nutrition therapy
  - Assessment of the need for continued nutrition support
  - Periodic review of the psychosocial status (patient and/or caregiver) and home environment of the patient
  - Monitoring of fluid, nutrient, and oral intake
  - Monitoring of urine, stool, and other gastrointestinal losses or output
  - Review appropriateness of the route of administration
- 22.3. PN or EN should be modified or discontinued when indicated by the severity or magnitude of associated complications.
- 22.3.1. Protocols shall be developed to identify mechanical, metabolic, and infectious complications necessitating interruption of nutrition support.

- 22.4. Communicate and document the results of the patient monitoring process to the physician and other healthcare professionals involved in the patient's care.

## CHAPTER VI: Review and Revision of NCP

### Standard 23. Evaluation of NCP

The NCP is reviewed and revised as necessary.

- 23.1. The home PN and EN treatment and care plan shall be reviewed, evaluated, and updated by the referring physician, home care provider, and other healthcare professionals to determine overall appropriateness, effectiveness, and safety of the treatment.
- 23.2. Patients shall be reassessed to determine the effectiveness of care in meeting therapeutic goals. Revision of the NCP may be required when changes occur in the patient's clinical condition, response to therapy, environment or psychosocial status, drugs/therapy, or when nutrition goals are not met.
- 23.3. All revisions of the NCP shall be documented in the patient's medical record.
- 23.4. The route of nutrition support shall be periodically reassessed for adequacy, appropriateness, efficacy, and safety.

## CHAPTER VII: Transition and Termination of Therapy

### Standard 24. Transition Feeding

- 24.1. During the transition from PN to EN, or PN to oral intake, or EN to oral intake, the patient shall demonstrate tolerance to the final nutrition support regimen.
- 24.2. Adequate nutrient from oral intake should be demonstrated prior to discontinuing PN and or EN.
- 24.2.1. Oral nutrient intake should be documented.
- 24.2.2. When appropriate, PN or EN should be gradually decreased as oral intake increases so that overall adequate nutrient intake is sustained.
- 24.2.3. If oral nutrient intake is suboptimal, PN or EN should not be discontinued.
- 24.3. If follow-up nutrition care is indicated, written and/or verbal information is given to the patient/caregiver.

### Standard 25. Termination of Therapy

- 25.1. PN or EN should be terminated when the patient no longer benefits from therapy or the burden outweighs the benefit.<sup>1,28</sup>
- 25.2. Patients and/or their designated representative, according to patient's competence, shall be involved in decisions regarding the withdrawal of nutrition support.

25.3. Protocols shall exist to permit the discontinuation of PN and EN in accordance with patient advance directives, medical ethics, local practice standards, and current local, state, and federal law.

## CHAPTER VIII: Definitions

The following terms that are used in these standards have been defined previously in A.S.P.E.N. Guidelines and Standards or by other organizations as referenced.

*Automated Compounding Device.* A device used in the preparation of PN. It automates the transfer of dextrose, amino acids, fat emulsion, sterile water, as well as small-volume injectables, such as electrolytes and minerals to the final PN container. The device is driven by computer software.

*Beyond-Use Date.* The date established by health-care professionals from the published literature or manufacturer-specific recommendations beyond which the pharmacy-prepared product should not be used.

*Care Plan.* Plan of professional clinical activities developed to implement the treatment plan.

*Clinical Guidelines.* Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.<sup>29</sup>

*Compatibility.* The ability to combine 2 or more chemical products such that the physical integrity of the products is not altered. Incompatibility refers to concentration-dependent precipitation or acid-base reactions that result in physical alteration of the products when combined together.

*Drug-Drug Interaction.* An event that occurs when a drug's activity, availability, or effect is altered by another drug.

*Drug-Nutrient Interaction.* An event that occurs when nutrient availability is altered by a medication, or when a drug effect is altered, or an adverse reaction caused by the intake of nutrients.

*Enteral Access Devices.* Tubes placed directly into the gastrointestinal tract for the delivery of nutrients or drugs.

*Enteral Nutrition (EN).* Nutrition provided through the gastrointestinal tract via a tube, catheter, or stoma that delivers nutrients distal to the oral cavity.

*Oral.* EN taken by mouth.

*Tube.* EN provided through a tube, catheter, or stoma that delivers nutrients distal to the oral cavity.

*Expiration Date.* The date established from scientific studies to meet the FDA regulatory requirements for commercially manufactured drug products beyond which the product should not be used.

*Formulation.* A ready-to-administer mixture of nutrients.

*Hang Time.* The period of time beginning with the

flow of a fluid through an administration set and catheter or feeding tube and ending with the completion of the infusion.

*Indicators.* Prospectively determined measures used as normative standards within a performance improvement process.

*Intravenous Fat Emulsant (IVFE).* An IV oil-in-water emulsion of oil(s), egg phosphatides, and glycerin. The term should be used in preference to lipids.

*Malnutrition.* Any disorder of nutrition status, including disorders resulting from a deficiency of nutrient intake, impaired nutrient metabolism, or overnutrition.

*Nutrition Assessment.* A comprehensive approach to defining nutrition status that uses medical, nutrition, and medication histories; physical examination; anthropometric measurements; and laboratory data. A formal nutrition assessment should provide all of the information necessary to develop an appropriate NCP. Because of the inextricable relationship between malnutrition and severity of illness and the fact that tools of nutrition assessment reflect both nutrition status and severity of underlying disease, an assessed state of malnutrition or presence of specific indicators of malnutrition in fact refers to the consequences of a combination of an underlying illness and associated nutrition changes and deficits.

*Nutritionally-at-Risk Adults.* Adults are considered at nutrition risk if they have any of the following:

- Actual or potential for developing malnutrition (involuntary loss or gain of  $\geq 10\%$  of usual body weight within 6 months or  $\geq 5\%$  of usual body weight in 1 month, a weight of 20% over or under ideal body weight), presence of chronic disease, or increased metabolic requirements.
- Altered diets or diet schedules (receiving total PN or EN, recent surgery, illness, or trauma).
- Inadequate nutrition intake, including not receiving food or nutrition products (impaired ability to ingest or absorb food adequately) for  $>7$  days.

*Nutritionally-at-Risk Children.* Children should be considered at nutrition risk if they have:

- A weight/length or weight for height less than the 10<sup>th</sup> percentile or greater than the 90<sup>th</sup> percentile.
- Increased metabolic requirement.
- Impaired ability to ingest or tolerate oral feedings.
- Documented inadequate provision or tolerance of nutrients.
- Inadequate weight gain or a significant decrease in an individual's usual growth percentile.

*Nutritionally-at-Risk Neonates.* Neonates should be considered at nutrition risk if they have:

- Very low birth weight (<1500 g) or low birth weight (<2500 g), even in the absence of gastrointestinal, pulmonary, or cardiac disorders.
- Birth weight <2 standard deviations below the mean (approximately the 3<sup>rd</sup> percentile for gestational age on fetal weight curves).
- Acute weight loss of 10% or more.

**Nutrition Care.** Interventions and counseling of individuals on appropriate nutrition intake through the integration of information from the nutrition assessment.

**Nutrition Care Plan (NCP).** A formal statement of the nutrition goals and interventions prescribed for an individual using the data obtained from a nutrition assessment. The plan, formulated by an interdisciplinary process, should include statements of nutrition goals and monitoring parameters, the most appropriate route of administration of specialized nutrition support (oral, enteral, and/or parenteral) method of nutrition access, anticipated duration of therapy, and training and counseling goals and methods.

**Nutrition Screening.** A process to identify an individual who is malnourished or who is at risk for malnutrition to determine if a detailed nutrition assessment is indicated.

**Nutrition Support Service (or Team).** A multidisciplinary group of healthcare professionals, including a physician, nurse, dietitian, and pharmacist with expertise in nutrition, who manage the provision of SNS.

**Nutrition Therapy.** A component of medical treatment that includes oral nutrition, EN, and PN.

**Oral Nutrition.** Nutrition taken by mouth.

**Outcome.** The measured result of the performance of a system or process.

**Parenteral Nutrition (PN).** The administration of nutrients intravenously.

**Central.** PN delivered into a large-diameter vein, usually the superior vena cava.

**Peripheral.** PN delivered into a peripheral vein, usually of the hand or forearm.

**Pediatric.** Patients  $\leq$  17 years old, including premature newborns, neonates, infants, toddlers, children, and adolescents.

**Specialized Nutrition Support (SNS).** Provision of nutrients orally, enterally, or parenterally with therapeutic intent. This includes, but is not limited to, provision of total EN or PN support to maintain and/or restore optimal nutrition status and health.

**Stability.** The extent to which a product retains, within specified limits and throughout its period of storage and use (ie, its shelf life), the same properties and characteristics that it possessed at the time of its manufacture.

**Standard.** Benchmark representing a range of performance of competent care that should be provided to assure safe and efficacious nutrition care.

**Total Nutrient Admixture (TNA).** A PN formulation containing IVFE as well as the other components of PN (carbohydrate, amino acids, vitamins,

minerals, trace elements, water, and other additives) in a single container.

**Treatment Plan.** Orders established and signed by a clinician with prescriptive rights for the care of the patient (ie, the medical orders, including nutrients, medications, activity orders, access site orders, etc).

**Vascular Access Devices (VAD).** A device inserted into a vein that permits administration of intermittent or continuous infusion of parenteral solutions or medications.

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