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October 24, 2016

B. Vindell Washington, MD, MHCM, FACEP National Coordinator for Health Information Technology U.S. Department of Health and Human Services Hubert H. Humphrey Building, Suite 729D 200 Independence Ave. SW Washington, DC 20201

Submitted electronically on http://www.healthit.gov

RE: ONC 2017 Draft Interoperability Standards Advisory Comments

Dear Dr. Washington:

The Academy of Nutrition and Dietetics (Academy) appreciates this opportunity to comment on the 2017 Interoperability Standards Advisory. Representing more than 100,000 registered dietitian nutritionists (RDNs),¹ nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation's health through food and nutrition across the lifecycle.

As nutrition and dietetics professionals, the Academy has participated in the regulations, comment opportunities, and related health IT standards development since 2010. We are committed to supporting improved health through quality nutrition care based upon evidence-based scientific guidance. In particular, Academy work during the past two decades has provided a sound foundation for nutrition inclusion in health IT standards. As one of the first professional groups to embrace evidence-based practice, the Academy created the world's first evidence-analysis nutrition library and produces guides for condition-specific nutrition care. The Academy's Nutrition Care Process (NCP)² provides a systematic process for nutritionists/dietitians to provide individualized high quality nutrition care. The NCP provides distinct, interrelated steps that include nutrition assessment, nutrition diagnosis, nutrition intervention and monitoring/evaluation. The NCP has been integrated into Health Level Seven (HL7) standards which allow for nutrition data to be included in varied care situations and in transitions of care content across care settings. The Academy's electronic Nutrition Care Process Terminology (eNCPT) which supports the NCP, has been mapped to now mandated terminologies, such that semantically correct nutrition terms be used consistently in U.S. health information technology. Ongoing work to align nutrition care terms across care settings is in process.

An important highlight of our comments relate to the development of Malnutrition Awareness Efforts -The Malnutrition Quality Improvement Initiative (MQii) which began in 2013 when a variety of stakeholder organizations began to highlight gaps in existing malnutrition care and the impact of these gaps on patient outcomes. Based on the results of subsequent literature reviews, landscape assessments, engagements with key stakeholders, and best practices research, the MQii was established in partnership with the Academy of Nutrition and Dietetics (Academy), Avalere Health, and other stakeholders providing guidance through key technical expert and advisory roles. The engagement was undertaken to advance evidence-based, high-quality patient-driven care for hospitalized older adults (age 65 and older) who are malnourished or at-risk for malnutrition.

¹ The Academy recently approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

² Nutrition Care Process website: http://www.eatrightpro.org/resources/practice/nutrition-care-process accessed October 24, 2016.

There is increasing evidence that malnutrition can negatively impact patient outcomes. In September 2016 AHRQ released a new statistical brief presenting national data on U.S. hospital discharges involving malnutrition demonstrating the significant burden that hospitalized patients with malnutrition face. Patients tend to be older, have longer lengths of stay, and have up to 100% costlier episodes of inpatient care (up to \$25,000 vs. \$12,500), were half as likely to be discharged home and 4.9 times more likely to result in in-hospital death than the average of all inpatient nonmaternal/non-neonatal stays.³

The MQii has developed and tested four electronic clinical quality measures (eCQMs). These four eCQMs address four of the major stages of the NCP including screening of all patients admitted to the hospital usually performed by nursing staff, completing a full nutrition assessment by a registered dietitian for patients screened as at-risk of malnutrition, the development of a nutrition care plan based on the dietitian's recommendations and finally the documentation of a malnutrition diagnosis by the clinician in the patient's medical record. Value sets have been established in the Value Set Authority Center for use in the Malnutrition eCQMs.

Malnutrition Value Sets

- Malnutrition Risk Screening Grouping Value Set (OID: 2.16.840.1.113762.1.4.1095.40)
- Malnutrition Screening At Risk SNOMEDCT Value Set (OID: 2.16.840.1.113762.1.4.1095.38)
- Malnutrition Assessment Grouping Value Set (OID: 2.16.840.1.113762.1.4.1095.29)
- Nutritional Status Severely Malnourished Grouping Value Set (OID: 2.16.840.1.113762.1.4.1095.43)
- Nutritional Status Moderately Malnourished Grouping Value Set (OID: 2.16.840.1.113762.1.4.1095.47)
- Malnutrition Diagnosis Grouping Value Set (OID: 2.16.840.1.113762.1.4.1095.55)

We recommend inclusion of these Malnutrition eCQMs in upcoming Quality Measurement Guidance. Due to the need for implementation guidance in all eCQMs, we request additional Implementation Specifications development for EHR vendors and implementers who wish to utilize accurate clinical data documentation as a component of data collection for eCQMs.

As an overview, we are including a summary of key areas where nutrition content has been developed and/or added to existing standards in the table at the end of this letter. These specific comments support our key requests:

- Include "Nutrition Status" as an expected component of patient-specific content in health IT and as a data element in the Common Clinical Data Set. This is supported by a Value Set in VSAC (2.16.840.1.113883.1.11.20.2.7) and across multiple other HL7 standards, including transitions of care. All other relevant areas of a patient's ability to perform daily living activities are included (physical activity, mobility, etc.).
- 2. Provide support for creation of an HL7 Implementation Specification for the successful reporting of eCQMs.
- 3. Provide nutrition specific content identified in our comments as "Applicable Starter Sets" and "Starter Sets" for nutrition related content in the ISA.
- 4. Provide additional support for pilot testing and guidance of key health IT standards, such as the C-CDA R2.1 STU. Due to the comprehensive content in the R2.1 STU, there remains a need for testing, refinement and guidance that will lead to widespread implementation.

Again, the following table provides an overview of nutrition content in health IT standards. Comments by specific area are included in the Excel ISA Template attached. We appreciate the opportunity to provide feedback concerning nutrition and dietetics practitioners and remain dedicated to promoting standards maturity and implementation due to the considerable impact sound nutrition care can provide to patients.

³ Weiss AJ, Fingar KR, Barrett ML, Elixhauser A, Steiner CA, Guenter P, Brown MH. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD. <u>http://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.pdf</u>.

Thank you for this opportunity to comment on the 2017 Draft Interoperability and Standards Advisory. Please direct questions and/or comments to Lindsey Hoggle, at phone number 1 (800) 877-0877, ext. 6014 or by e-mail at https://www.lindsey.org.

Sincerely,

Kindsey Hoggle MS, RDN, PMP

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Alm L Steiler -

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TABLE Nutrition in Health IT Standards Summary

The Health Level Seven International once quoted, "successful semantic interoperability requires vocabularies to be harmonized across all standards and implementation guides that express the same concepts."

Much work has been done in the area of nutrition to develop standards and value sets that support the goals of interoperability. Nutrition domain experts have worked within HL7 to develop and incorporate the Nutrition Care Process and related nutrition content (including Nutrition Care Process Terminology developed in 2004) into many balloted standards.

The <u>HL7 EHR-System Electronic Nutrition Care Process Record System (ENCPRS) Functional Profile,</u> <u>Release 1</u> identifies critical capabilities for the performance of nutrition services utilizing EHR systems. The normative <u>HL7 V3 Domain Analysis Model: Diet and Nutrition Orders, Release 2</u> provides a detailed information model for the exchange of nutrition orders including oral diets, enteral nutrition (tube feeding and infant formula) and oral nutritional supplements which along with food allergies, food intolerances and food preference information are required to safely feed all patients and to effectively treat those who are malnourished.

Value sets in the Value Set Authority Center covering nutrition therapy diet intervention include:

- Food and nutrient delivery (OID 2.16.840.1.113762.1.4.1095.2)
- Adult and pediatric enteral formula products (OID 2.16.840.1.113762.1.4.1095.16,
- 2.16.840.1.113762.1.4.1095.5, OID 2.16.840.1.113762.1.4.1095.17)
- Modular enteral components (OID 2.16.840.1.113762.1.4.1095.7)

These represent the collaborative work of nutrition, vocabulary and HL7 modeling experts where progress has been reviewed over the course of several HL7 Working Group Meetings in the past few years. We encourage all EHR vendors to align their nutrition content and documentation with these standards including the structured content and terminology value sets that can populate the Nutrition section-level templates that are part of C-CDA, R2.1, as well as the proposed Malnutrition -measures. Nutrition content within HL7 standards are included in a variety of different areas, as nutrition care transects all areas of care and treatment plans for individuals.

HL7 Standard	Description of nutrition content
HL7 EHR-System Electronic	The ENCPRS Functional Profile provides high-level
Nutrition Care Process Record	requirements necessary for using electronic health record data
System (ENCPRS) Functional	for Dietetics and Nutrition Practice using the Nutrition Care
Profile, Release 1	Process, the eNCPT, and further defines the required nutrition
(HL7 ENCPRS-FP)	

HL7 Standard	Description of nutrition content
	data necessary to support data collection for both patient care
	and dietetics and nutrition practice-based research.
	We encourage all EHR vendors to review their existing nutrition
	content and incorporate these critical functions into their
	products.
HL7 Domain Analysis Model: Diet	The Diet and Nutrition Orders DAM provides the information
and Nutrition Orders, Release 2	model for the electronic transmission and exchange of nutrition
	orders including oral diets, enteral nutrition (tube feeding and
	infant formula) and oral nutritional supplements which along with
	food allergies, food intolerances and food preference information
	are required to safely provide inpatients or residents with
	nutritionally appropriate foods. Terminology examples
	referencing value sets in VSAC and SNOMED CT US Extension
	are included. The following standards were informed by and
	conform to this work: V3 Nutrition Orders Clinical Messages, V3
	Food and Medication Preferences, and FHIR NutritionOrder
	resource.
HL7 Version 3 Domain Analysis	The Allergy and Intolerance DAM creates a standard model to
Model: Allergy and Intolerance,	support documenting and exchanging allergy and intolerance
<u>Release 1</u>	data within institutional electronic health records along with a
	proposed model to share this information with other systems
	including Personal Health Records. It outlines a clear set of use
	cases covering drug, food, device and environmental adverse
	reactions to support the C-CDA, FHIR, CDS and vMR. It allows
	for the creation of value sets to standardize the substances and
	products associated with adverse reactions. Ongoing work
	within the HL7 Patient Care Work Group seeks to create value
	sets to improve functionality of existing "allergy lists" within
	EHRs. The Patient Care WG has compiled multi-institutional
	data from over 40 million patient's food allergy frequency data.
	Extensive work to submit a comprehensive list of foods and food
	categories to the Substance hierarchy of SNOMED-CT has
	been completed. We request that all EHR vendors utilize the
	collaboration of this WG and utilize a Value Set to be created by
	the HL7 Patient Care Work Group in the near future. The status
	of this work can be referenced at: Project Summary for Allergy
	and Intolerance Substance Value Set(s) Definition Informative.
HL7 FHIR - NutritionOrder	A request to supply a diet, formula feeding (enteral) or oral
(Request) Resource	nutritional supplement to a patient/resident. The
(STU 3 Sept 2016 Ballot)	NutritionRequest resource describes a request for oral diets
	(including general diets such as General Healthy diet, or
	therapeutic diets such as Consistent Carbohydrate, 2 gram
	Sodium, or Fluid Restricted), oral nutrition supplements (such as
	nutritionally formulated pre-packed drinks), enteral nutrition
	(tube feedings) and infant formula which govern the distribution
	of food and nutritional products used to feed patients within an
	in-patient setting. These nutrition orders inform healthcare
	personnel and caregivers about the type, texture, and/or
	quantity of foods that the patient should receive or consume.
	Note: This resource was tested as part of an educational
	session demonstration at HIMSS16—Nutrition on FHIR: Burning
	Calories and More for your EHR.
	http://www.himssconference.org/sites/himssconference/files/pdf/
	185.pdf
	100.001

HL7 Standard	Description of nutrition content
HL7 Version 3 Standard: Diet and Nutrition, STU Release 1	The V3 Nutrition Orders standard is a universal realm messaging specification intended to standardize the electronic transmission and exchange of nutrition orders including oral diets, enteral nutrition (tube feeding and infant formula requirements) and nutritional supplements in health care facilities across the continuum of care. It was informed by and conforms to the Domain Analysis Model: Diet and Nutrition Orders standard.
<u>HL7 Personal Health Record</u> <u>System Functional Profile</u>	The Personal Health Record System Functional Model specifies the features and functions necessary to enable an individual to manage information about his or her healthcare within a PHR and exchange that information with other systems including EHR systems, payer/insurer systems and other collaborative care systems. The functions include activities such as managing wellness, prevention and encounters. Nutrition-related features and functions are outlined in PH 2.5.11 include capabilities to allow an individual to record and monitor food and nutrient intake, track physical activity and exercise and include education and diet recommendations provided by a Registered Dietitian. These capabilities may be supported by data imports from wearables, activity trackers and other remote monitoring devices. Together, these functions are designed to encourage and allow an individual to participate actively in their healthcare and better access the resources that allow for self-education and monitoring.
Consolidated Clinical Document Architecture R2.1	 Nutrition content is included in 7 C-CDA R2.1 transition of care documents, using a NEW Section Level template, three entry level templates and multiple care team specific templates such as the Plan of Treatment, Health Concerns, etc. The <i>Nutrition Section</i> (OID 2.16.840.1.113883.10.20.22.2.57) represents diet and nutrition information including special diet requirements and restrictions (e.g., texture modified diet, liquids only, enteral feeding). It also represents the overall nutritional status of the patient and nutrition assessment findings. The C-CDA 2.1 contains three entry level templates: <i>Nutrition Assessment</i> (OID 2.16.840.1.113883.10.20.22.4.138) represents the patient's nutrition abilities and habits including intake, diet requirements or diet followed. <i>Nutrition Status Observation</i> (OID 2.16.840.1.113883.10.20.22.4.124) Represents the overall nutritional status of the patient including findings related to nutritional status. The <i>Nutrition Assessment</i> supports the finding in the <i>Nutrition Status Observation</i>. <i>Nutrition Recommendation</i> (OID 2.16.840.1.113883.10.20.22.4.130) is an entry level template in the Plan of Treatment Section and represents nutrition regimens (e.g., fluid restrictions, calorie minimum), interventions (e.g., NPO, nutritional supplements), and procedures (e.g., G-Tube by bolus, TPN by central line). It may also depict the need for nutrition education.

HL7 Standard	Description of nutrition content
	Value sets are maintained in VSAC to support the section and entry level templates. In addition, the Academy plans to develop an HL7 C-CDA R2.1 Nutrition Specific Implementation Specification.
Pressure Ulcer Prevention Domain Analysis Model	This DAM represents information used in assessing pressure ulcer risk, including existing pressure ulcers. This work also includes preliminary work on interventions for pressure ulcers. Nutrition-specific content supports the care involving increased nutritional needs in individuals with pressure ulcers.
Developmental Screening Derived Domain (Child Health) Profile and the EHR Child Health Functional Profile Release 1	This work is designed to assist children's healthcare providers and associated IT vendors to create functionality that ensures safe and reliable care of children through the effective use of information technology. Nutrition specific content necessary for the developmental needs of children are included.
<u>Terminology Harmonization in</u> <u>Exercise Medicine and Exercise</u> <u>Science (THEMES) Data Standards</u> <u>Project</u>	This NEW work on exercise terminology development The goal of this project is to develop a Domain Analysis Model that will address major concept, data elements, and data interoperability barriers that have impeded the use of physical activity and exercise outcomes in translational research and in clinical applications.
	This work intends to harmonize and present Current terminologies used in clinical Cardiopulmonary Exercise Testing (CPET) derived from major texts and published guidelines used nationally and internationally, Exercise and physical activity terms used by national societies such as the American Thoracic Society, American College of Sports Medicine, and the American Heart Association, Cystic Fibrosis Foundation, etc., and Exercise and physical activity variables used in large data sets associated with clinical trials (e.g., NHANES, CARDIA, Project Healthy). While nutrition per se is not in scope, this work supports evidence based exercise guidance which align with wellness and disease prevention.
<u>HL7 Version 3 Domain Analysis</u> <u>Model: Behavioral Health Record,</u> <u>Release 2</u>	The goal of this DAM is to improve the health of at-risk populations by improving care coordination between specialty behavioral health, primary care, and related human service providers, through systems interoperability. The content in this DAM assumes nutritionist intervention in the care of patients with behavioral health needs and that nutrition requirements of humans for proper health and development are addressed. Content pertaining to government food assistance programs is included.
HL7 Version 3 Standard: Care Provision; Assessment Scales, Release 1	Healthcare uses numerous tests, scales and assessment instruments. These require a strict precision to naming, coding, and representing them in health care information technology. Nutrition Assessment instruments referenced include the Mini- Nutritional Assessment; additional validated instruments are available.
Integrating the Healthcare Enterprise (IHE) Healthy Weight Profile	Childhood obesity surveillance systems utilize either measured (e.g. NHANES) or parent/self-report height and weight to calculate BMI. The IHE Healthy Weight (HW) profile established methods to capture and communicate this information in a structured way not only for public health surveillance system, but also addresses care management for healthy weight clinical

HL7 Standard	Description of nutrition content
	assessment and interventions. This standard utilizes the Clinical Document Architecture standard. The Academy participated in a multi-collaborative session at the HIMSS Interoperability Showcase in 2014 which demonstrated nutrition inclusion in a Healthy Weight Plan, created and shared by physician, patient and nutritionist via the Referral Note using the C-CDA R2.0 DTSU.