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March 1, 2017

Shantanu Agrawal, MD
President & CEO
National Quality Forum
1030 15th Street, NW
Suite 800
Washington, DC 20005

Re: Comments for NQF Improving Diagnostic Quality and Safety: Draft Measurement Framework

Dear Dr. Agrawal:

On behalf of the Advanced Medical Technology Association (AdvaMed) and AdvaMedDx, we appreciate the opportunity to comment on the National Quality Forum's *Draft Measurement Framework for Improving Diagnostic Quality and Safety*.

AdvaMedDx member companies produce advanced *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx deals exclusively with issues facing *in vitro* diagnostic manufacturers both in the United States and abroad. Throughout this letter, AdvaMed refers to both AdvaMed and AdvaMedDx.

I. General Comments:

AdvaMed commends the National Quality Forum for taking up the challenging and important issue of quality measurement for improving diagnostic quality and safety. NQF's focus on diagnostic quality highlights the value of diagnostic testing, and particularly the importance of diagnostics. Diagnostic tests account for only a small fraction of health expenditures, yet they provide important information that can significantly influence health care decision-making. Diagnostic tests are an essential component in the health care continuum and are sometimes undervalued. Importantly, diagnostic testing serves to address important unmet medical needs.

We agree with the NQF committee assessment that the scope should be expanded to encompass improving diagnostic safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability, as these dimensions apply to diagnosis. We also support the recommendation to

align the preliminary draft framework to the National Academies of Sciences, Engineering and Medicine (NASEM) conceptual model of the diagnostic process.

AdvaMed has long supported the use of appropriate quality measures in all settings to improve the quality of patient care and patient safety. Many quality measures are aimed at providing early diagnosis, timely treatment decisions and treatment delivery, which can lead to reduced patient morbidity and mortality, improved patient quality of life and contribute to lowering the over-all cost of care.

It is important to note that when it comes to diagnostics, there are many different paths and players along the diagnostic journey. A laboratory may perform a test, which may then be interpreted by a pathologist who relays the result to a clinician who makes a medical decision, or a referral for care, perhaps with or without the input of the patient. Various medical providers may communicate different information to patients and their caregivers over the course of the journey, and clinically-related decisions are made or not made based on that information. In addition, it is important to note that there is unnecessary waste in the healthcare system when patients go through a medical odyssey with inaccurate diagnoses.

Measure development related to diagnostic testing needs to be clear regarding who is being evaluated and at what point in time. As noted on the NASEM website, there are numerous stories provided to illustrate the significant issues surrounding communication/miscommunication between treating clinicians and patients, as well as between treating clinicians concerning the reasoning for the ordering of the test, the test results and future implications. The draft NQF Measure Concept Framework provides a starting point for addressing these communication errors and avoiding unnecessary and unintentional patient harms and waste in the healthcare system.

In developing measure concept and subsequent clinical measures, measure stewards need to be keenly aware of the innovations that are taking place at a rapid pace in diagnostic testing. For example, molecular diagnostics is becoming an increasingly important determinant of diagnosis, treatment selection and patient monitoring. These testing methods are becoming increasingly complex. Molecular tests that initially identified single mutations now often are complex multi-marker panels generated by advanced next generation sequencing technologies and interpreted by proprietary algorithms. These are the transformative advances enabling precision medicine, but they also are creating an increasingly difficult landscape for laboratorians, clinicians and patients to understand and navigate effectively.

Innovations in diagnostic technologies also are shifting some testing outside the laboratory, which raises additional considerations regarding the interpretation, communication, and use of test results. Point-of-care tests can be performed and deliver time-sensitive results in a wide variety of care settings, including the emergency room, the hospital bedside, the doctor's office, and the clinic. Emerging in-vivo diagnostic technologies, of which continuous glucose monitors are an early example, will enable the collection, transmission, and interpretation of patient-generated data and empower earlier and more effective health interventions by patients and clinicians alike.

Therefore, the context of when and how different tests should be incorporated into standard practice is constantly evolving to keep pace with the technological/clinical innovations which are occurring. As personalized medicine becomes more and more available, the need for these concepts and correct and timely communication becomes increasingly necessary. Thus, measure concepts related to education of providers and their communication to other providers and patients regarding diagnostic testing along the patient journey will be an essential component in future measures.

As noted in the draft framework report, a significant portion of the concepts were based on the National Academies of Sciences, Engineering and Medicine's (NASEM's) study titled *Improving Diagnosis in Health Care*.¹ We believe that many of the goals contained in the report aimed at reducing diagnostic error and improving diagnosis address many significant considerations when developing quality measures in this landscape including:

- Facilitating more effective teamwork in the diagnostic process among health care professionals, patients, and their families including coordination of care;
- Enhancing health care professional education and training in the diagnostic process;
- Ensuring that health information technologies (IT) support patients and health care professionals in the diagnostic process;
- Developing and deploying approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice; and
- Establishing a work system and culture that supports the diagnostic process and improvements in diagnostic performance.

II. Recommendations for Future Measures and Measure Concepts to Improve Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability

As the committee considers measure concepts that align with the structure, process and outcomes domains and sub-domains outlined in "Appendix C", we urge NQF to also consider potential, as well as existing measures that could be adopted immediately to fill these diagnostic quality measure gaps.

a. Potential Measure Concepts:

i. Recommendation to Include Shared Decision Making in Considering Use of New Technologies in Patient Care.

AdvaMed applauds NQF for considering numerous measure concepts related to patient engagement and workflow as noted in Appendix C. In this regard, AdvaMed recommends that NQF incorporate the concept of shared decision making for discussion of new technologies in patient care. The activity would encourage practitioners and groups to take time and provide thoughtful engagement with their patients when potential new diagnostic technologies may be

¹ National Academies of Sciences, Engineering and Medicine. 2015. *Improving diagnosis in health care*. Washington, DC: The National Academies Press.

used as an option in their care. For some practitioners, this would allow them a new way to practically incorporate new technology and new procedures in their practice for the benefit of their patients. Additionally, this concept would aid in achieving improved beneficiary health outcomes and reducing health care disparities.

ii. Recommendation to Include Providing Timely Access to Medical Diagnostic Technologies

AdvaMed is pleased that the draft framework addresses many of the timeliness issues related to the diagnostic process subdomain; however we also recommend that there should be similar emphasis on providing timely patient access to diagnostic technologies. For example, the ability to complement existing colorectal cancer diagnostic testing with innovative technologies such as colon capsule endoscopy may be a viable solution for improving access of this important diagnostic test for patients in rural areas, patients at high risk for a colonoscopy or patient populations with low engagement. Ensuring that diagnostic testing aligns with the most current clinical guidelines and standards is another important measure concept. As innovations in diagnostic testing are rapidly evolving it is important that the right test is conducted in the right population at the right time. In addition, it is important to provide timely access to medical diagnostics for patients in need of social services including disabled patients and underserved populations to ease the healthcare burden. AdvaMed believes that timely access to diagnostic technology is a key component to the success of any quality measure concepts to address timely diagnosis and assessment of a patient's health problem.

b. Existing Quality Measures for Adoption:

i. Malnutrition Electronic Clinical Quality Measures (eCQMs):

NQF is currently considering a malnutrition measure set for endorsement that includes a diagnosis-related measure that could be adopted to fill diagnostic quality measure gaps. In addition, CMS is considering these measures for the inpatient quality reporting program.

The measure steward, the Academy of Nutrition and Dietetics and Avalere Health, developed a set of electronic clinical quality measures (eCQMs) for malnutrition that includes a diagnosis-related measure, described in more detail in Appendix A. The Appendix outlines how the malnutrition eCQM measure set aligns with the proposed domains and sub-domains for improving Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability.

Timely screening, diagnosis and treatment of malnourished or patients at risk for malnutrition is critical to improving outcomes¹ and patient safety by reducing complications that can lead to readmissions including infections, falls, and pressure ulcers. Documentation of Diagnosis is key component in the diagnostic and care process, as it triggers interventions linked to improved outcomes. In the case of malnutrition, the dietitian conducts an assessment, documents malnutrition findings and makes a recommendation of nutritional status in the medical record; but until the physician documents the diagnosis, the care plan implementation and care coordination is not consistently triggered. This example supports the existence of a measure gap

and the opportunity to improve diagnostic safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability with adoption of the malnutrition eCQMs. Again, Appendix A provides additional information regarding this measure set, which is being considered by CMS for adoption in the Hospital Inpatient Quality Reporting program.

AdvaMed appreciates this opportunity to share our feedback and comments to NQF regarding the *Draft Measurement Framework for Improving Diagnostic Quality and Safety*. AdvaMed looks forward to working with NQF as it continues on this important activity. We understand that there will be multiple opportunities available to participate in public meetings or to comment on the proposed framework, quality measure concepts, or other related proposals, and we look forward to participating and contributing.

Please contact me or Steven J. Brotman, MD, JD at sbrotman@advamed.org if you have any additional questions or need any additional information.

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Donald May
Executive Vice President,
Payment and Health Care Delivery

Appendix A:

Malnutrition eCQMs Align with Improving Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability

Domain/Subdomain	Examples of Measure Concepts	Malnutrition eCQM Examples
<p>Structure/Technologies & Tools</p> <ul style="list-style-type: none"> • Clinical Content of HIT • Availability of diagnostic resources 	<ul style="list-style-type: none"> • The organization uses an interoperable and certified eHR that integrates nutrition data standards, CCDA 2.0 and CDS functionality • eHR allows for designating patients as “not yet diagnosed (NYD)” 	<ul style="list-style-type: none"> • NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients
<p>Structure/External Environment</p> <ul style="list-style-type: none"> • Care Delivery System • Reporting environment 	<ul style="list-style-type: none"> • Care delivery system promotes care coordination • Care delivery is patient-centered, not physician centered 	<ul style="list-style-type: none"> • NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
<p>Process- Patient Engagement</p> <ul style="list-style-type: none"> • Access to Care • Communication with Patient 	<ul style="list-style-type: none"> • Communication about the diagnosis is documented 	<ul style="list-style-type: none"> • NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
<p>Process- The Diagnostic Process</p> <ul style="list-style-type: none"> • Eliciting patient history & performing the <i>nutrition-focused physical assessment</i> • Integration of team-based information • Consultation from specialists • Appropriate follow-up 	<ul style="list-style-type: none"> • Adequacy of documenting the initial findings; clarity and accuracy of the documentation • Proportion of patients with timely follow up after initial diagnosis • Diagnosis is timely 	<ul style="list-style-type: none"> • NQF #3087 Malnutrition Screening within 24 Hours of Admission • NQF #3088 Completion of Nutrition Assessment for Patients Identified as at-risk for malnutrition within 24 Hours of Malnutrition Screening • NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment • NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients

Domain/Subdomain	Examples of Measure Concepts	Malnutrition eCQM Examples
<p>Outcomes- Diagnostic Outcomes</p> <ul style="list-style-type: none"> • Timeliness of diagnosis 	<ul style="list-style-type: none"> • Timeliness of diagnosing targeted diseases of interest (anemia, asthma, diabetes, COPD, <u>malnutrition</u>) 	<ul style="list-style-type: none"> • NQF #3088 Completion of Nutrition Assessment for Patients Identified as at-risk for malnutrition within 24 Hours of Malnutrition Screening • NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients
<p>Outcomes- Patient</p> <ul style="list-style-type: none"> • Morbidity/mortality related to diagnostic error/failure 	<ul style="list-style-type: none"> • # of patients targeted through trigger tools designed to avoid harm 	<ul style="list-style-type: none"> • NQF #3087 Malnutrition Screening within 24 Hours of Admission • NQF #3088 Completion of Nutrition Assessment for Patients Identified as at-risk for malnutrition within 24

References

ⁱ Deutz et al. Clinical Nutrition 35 (2016) p. 18-26.