AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

February 16, 2016

Andrew M. Slavitt
Acting Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-3323-NC, P.O. Box 8013,
Baltimore, MD 21244-8013.

Submitted electronically via http://www.regulations.gov.

Subject: [CMS-3323-NC]
Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs

Dear Mr. Slavitt:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs published in the Federal Register [80 FR 81824] on December 31, 2015. This request for information seeks public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS) as well as the frequency of recertification and the number of clinical quality measures (CQMs) a certified Health IT Module should be required to certify to.

We are supportive of CMS' efforts to improve patient care and efficiency through quality measurement and payment evaluation. Orthopaedic surgeons have been at the forefront of the transition to value-based health care payments and we have made considerable investment in helping our members make this transition by developing evidence-based tools, (including clinical practice guidelines (CPGs), appropriate use criteria (AUCs), performance measures, and data registries) through standardized methodology and publication of transparent results.[1] The AAOS urges CMS to create adequate infrastructure for measure certification and development and

[1] More information on our work may be found on the AAOS website: http://www.aaos.org/Research/

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recommends measures be developed with quality and patient safety as guiding principles. Cost containment measures may result in short term gains but not long term improvement in quality. Working toward uniformity of measures can simplify data collection and evaluation and minimize duplication of effort on measure development. We also need more specialty specific measures.

The AAOS thanks CMS in advance for its solicitation and consideration of the following comments and concerns. We have structured our comments in the order that CMS is soliciting public feedback in the RFI document referenced above.

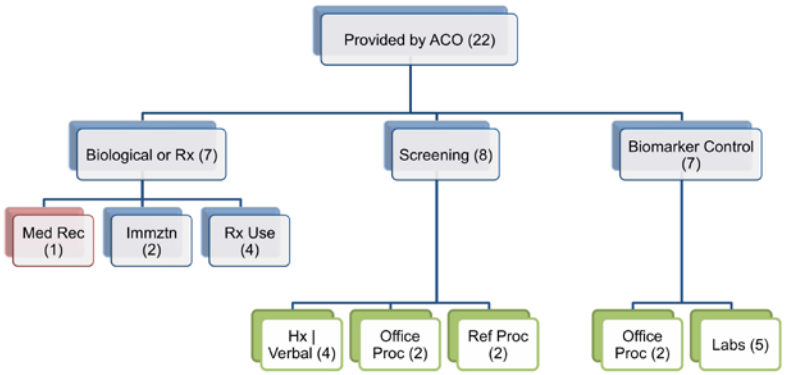
What, if any, adverse implications could the increased certification standards have on providers?

There are a number of challenges in functional requirements in reporting quality measures faced by small and large health care providers as well as health IT vendors. In order to meet certification and usability requirements, vendors and providers face considerable burden in capturing data to support quality measure mandates, monitoring measurement status in dashboards, and submitting results to various healthcare workflows. We believe that such time, effort and other resources should be dedicated to providing necessary health care and not enhancing technological inputs.

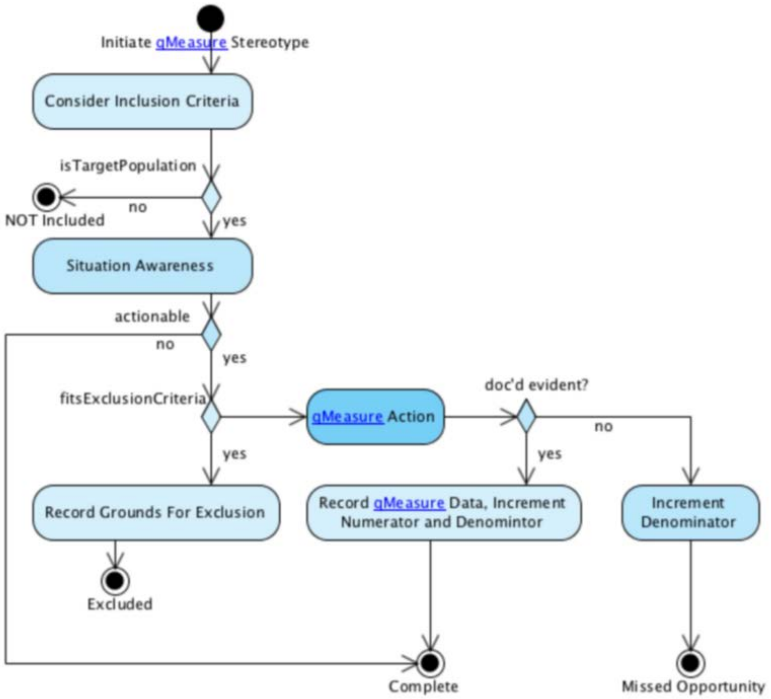
In addition, primary care and specialty medical practice workflow needs to be better understood. Quality measures required of providers need to be examined in terms of workflow and activity to simplify the process of capturing data needed for submission. To illustrate further, in some reviews of accountable care organization (ACO) performance measures, there exist at least seven stereotypes/domains in quality measures, each with different implications for data capture, status monitoring, and dashboard visualization. The quality measure stereotypes can further be broken down into immunization, screening & follow-up plan, office procedure, referred screening, lab-evident control, prescription use, and medication reconciliation – all with different workflows and multiple data sources. Though varied in numerous dimensions, common activities involve determination of patient inclusion, recording reasons for exclusion, acting on opportunities, and dissemination of events for distributed patient situation awareness. Below is a taxonomy of measure stereotypes and a typical workflow [2]:

[2] Tables used with permission: Steward, D. & Dew, D. (2014, February 23). Challenges in Functional Requirements for Quality Measurement Faced by Small Community Care Providers. The Physician Community. Retrieved from http://www.himss.org/ResourceLibrary/genResourceDetailPDF.aspx?ItemNumber=29787

Taxonomy of Measure Stereotypes



Main Use Cases



Quality measures include a number of domains such as preventive care, care coordination, or at-risk populations. The provider has to understand prevention versus a diagnosed problem, scope of inclusion criteria and scope of exceptions and exclusion criteria. Data requirements vary from autonomous to asynchronous access and synchronous access to limited access and. limited-by-proprietary versus arcane. Cardinality of intervention is important whether once per lifetime versus age threshold to interval bounded vs. ongoing. Other considerations include population scope (universal versus disease-specific versus as-needed/indicated conditional), action immediacy, resource requirements, external dependencies, documentation and audit requirements and provider interest.

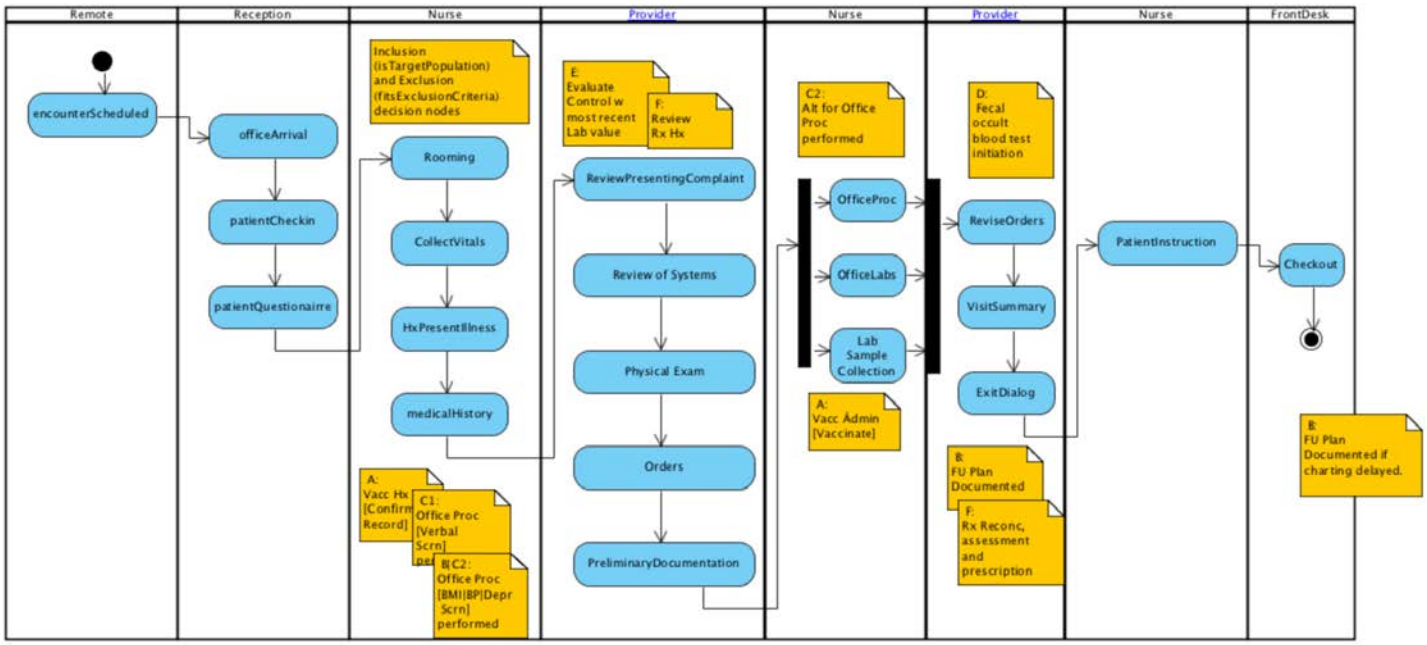
Another issue is that the readiness to measure quality in effective ways under present mandates poses many remaining questions both for vendors and providers. For example, the current practice for Meaningful Use (MU) and Physician Quality Reporting System (PQRS) Measurement submissions varies from non-existent, to well-adopted success, to severe reduction in caseload capacity.

What, if any, adverse implications could the increased certification standards have on providers?

Additional testing and recertification updates are another problem. There is a cost burden to the provider any time a "new" module is placed into an electronic medical record (EMR) system. This burden can come in many forms. For example, interoperability can be a problem with any new introductions to the systems both internally to the vendor and to outside systems. There are often extra charges for an additional module including interface and maintenance. Internal and external data bases may not populate needed data points when recording quality measures both in terms of the numerator, denominator, and any exclusion. While providers want to improve patient care, unfortunately, some of the test scripts do not apply to medical workflows, and do not contribute to improvement in patient care and communication.

What levels of testing will ensure that providers and other product purchasers will have enough information on the usability and effectiveness of the tool without unduly burdening health IT developers?

Many providers have limited control over certain quality measures. Laboratories, rehabilitation clinics, some specialists (e.g., ophthalmologist, neurologist), and even hospitalists may be constrained in which measures they can impact. This has a huge implication in that the number of use cases involving those with power to change scores is limited. The chart[1] below represents the information that can be collected in one ambulatory encounter as well as who and where it is being collected.



To avoid missed opportunities and eliminate duplication of effort, all network stakeholders must "know" the current state of measurements at the point of care. Thus, there is a unique demand for situational awareness with regard to each measure for dashboarding.

Would flexibility on the vocabulary codes allowed for test files reduce burden on health IT developers?

The Z code section of ICD-10 Clinical Modification lead to processes that will directly affect patient care and provider communication and improve the quality of care. The information regarding "Z00-Z99 Factors influencing health status and contact with health services," is embedded in all EMRs and could be included in all patient claims data. Most people are unfamiliar with this section since ICD-10 is often associated with diagnostic codes for billing. There is actually quite a bit of information that could be captured, but is not currently recorded in the medical record as a Z code. In contrast, this data is often being recorded as clinical information, but is not being coded, and therefore is excluded in the Medicare claims data and thus not available for analysis.

Using Z codes as process measures would not represent a large burden on vendor or provider. In the Appendix, we have included a few Z codes that could improve patient care, communication, and data if they were recorded in the claims data

In summary we would like to reiterate that any benefit of excessive testing and certification requirements to the patient is indirect at best, at least using existing quality measures. For example, measures that gauge the documentation of a follow-up plan for elevated body mass index (BMI) or blood pressure are extraneous indicators that the value-added planning and interaction did occur, but are not strictly essential to those value-additive investments of time and resource. Thus, quality measurement should be transparent to care delivery workflow for all partners accountable for care and there is a need for situational awareness at the point of care.

The AAOS appreciates the opportunity to comment, and looks forward to continued partnership with CMS to improve the clinical relevance, patient-centeredness, and value of quality measurement in healthcare delivery.

Sincerely,

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Appendix

Recommended Z codes to be used as process measures:

Z14.0 Hemophilia A carrier
Z14.1 Cystic fibrosis carrier
Z15.0 Genetic susceptibility to malignant neoplasm
Z16.10 Resistance to unspecified beta lactam antibiotics
Z16.11 Resistance to penicillins
Z16.12 Extended spectrum beta lactamase (ESBL) resistance
Z16.19 Resistance to other specified beta lactam antibiotics
Z16.20 Resistance to unspecified antibiotic
Z16.21 Resistance to vancomycin
Z16.22 Resistance to vancomycin related antibiotics
Z16.23 Resistance to quinolones and fluoroquinolones
Z16.24 Resistance to multiple antibiotics
Z16.31 Resistance to antiparasitic drug(s)
Z16.32 Resistance to antifungal drug(s)
Z16.33 Resistance to antiviral drug(s)
Z16.34 Resistance to antimycobacterial drug(s)
Z16.35 Resistance to multiple antimicrobial drugs
Z18.10 Retained metal fragments, unspecified
Z18.11 Retained magnetic metal fragments
Z18.12 Retained nonmagnetic metal fragments
Z22.5 Carrier of viral hepatitis
Z22.6 Carrier of human T-lymphotropic virus type-1 [HTLV-1] infection
Z45 Encounter for adjustment and management of implanted device
Z47.1 Aftercare following joint replacement surgery
Z47.2 Encounter for removal of internal fixation device
Z55.0 Illiteracy and low-level literacy
Z59.0 Homelessness
Z59.1 Inadequate housing
Z59.4 Lack of adequate food and safe drinking water
Z59.5 Extreme poverty
Z59.6 Low income
Z67.1 Type A blood
Z67.2 Type B blood
Z67.3 Type AB blood
Z67.4 Type O blood
Z68.1 Body mass index (BMI) 19 or less, adult

Z68.2 Body mass index (BMI) 20-29, adult
Z68.3 Body mass index (BMI) 30-39, adult
Z68.4 Body mass index (BMI) 40 or greater, adult
Z68.5 Body mass index (BMI) pediatric
Z79.0 Long term (current) use of anticoagulants and antithrombotics/antiplatelets
Z79.1 Long term (current) use of non-steroidal anti-inflammatories (NSAID)
Z79.2 Long term (current) use of antibiotics
Z79.3 Long term (current) use of hormonal contraceptives
Z79.4 Long term (current) use of insulin
Z79.5 Long term (current) use of steroids
Z79.8 Other long term (current) drug therapy
Z80 Family history of primary malignant neoplasm
Z81 Family history of mental and behavioral disorders
Z82 Family history of certain disabilities and chronic diseases (leading to disablement)
Z86.3 Personal history of endocrine, nutritional and metabolic diseases
Z86.5 Personal history of mental and behavioral disorders
Z87.3 Personal history of diseases of the musculoskeletal system and connective tissue
Z88.0 Allergy status to penicillin
Z88.1 Allergy status to other antibiotic agents status
Z88.2 Allergy status to sulfonamides status
Z88.3 Allergy status to other anti-infective agents status
Z88.4 Allergy status to anesthetic agent status
Z88.5 Allergy status to narcotic agent status
Z88.6 Allergy status to analgesic agent status
Z88.7 Allergy status to serum and vaccine status
Z88.8 Allergy status to other drugs, medicaments and biological substances status
Z88.9 Allergy status to unspecified drugs, medicaments and biological substances status
Z89 Acquired absence of limb
Z91.0 Allergy status, other than to drugs and biological substances
Z91.1 Patient's noncompliance with medical treatment and regimen
Z91.4 Personal history of psychological trauma, not elsewhere classified
Z91.5 Personal history of self-harm
Z92.2 Personal history of drug therapy
Z92.3 Personal history of irradiation
Z96.6 Presence of orthopedic joint implants
Z97.1 Presence of artificial limb (complete) (partial)
Z99.0 Dependence on aspirator
Z99.1 Dependence on respirator
Z99.2 Dependence on renal dialysis
Z99.3 Dependence on wheelchair