CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)

Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services (CMS)

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Executive Summary

Background

The passage of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) supports an ongoing transformation of health care delivery by furthering the development of new Medicare payment and delivery models for physicians and other clinicians.[1] Section 102 of MACRA[1] requires that the Secretary of Health and Human Services (HHS) develop and post on the CMS.gov website "a draft plan for the development of quality measures" by January 1, 2016, for application under certain applicable provisions related to the new Medicare Merit-based Incentive Payment System (MIPS) and to eligible Medicare alternative payment models (APMs).[i] CMS posted a draft plan on December 18, 2015, and solicited public comment.[2,3] Responses from 210 individual and institutional commenters informed the creation of this final CMS Quality Measure Development Plan (MDP). MACRA requires the plan to be posted on the CMS.gov website by May 1, 2016.[ii]

MACRA provides both a mandate and an opportunity for CMS to leverage quality measure development as a key driver to further the aims of the CMS Quality Strategy[4]:

- Better Care
- Smarter Spending
- Healthier People

Measure Development Plan Purpose

The purpose of the MDP is to meet the requirements of the statute and serve as a strategic framework for the future of clinician quality measure development to support MIPS and advanced APMs[iii] (referred to in MACRA as eligible APMs). The MDP highlights known measurement and performance gaps, such as those initially identified in Section V (Summary of Gaps and Priorities), and recommends prioritized approaches to close those gaps through the development, adoption, and refinement of quality measures. CMS draws from extensive experience in these processes in conjunction with cross-agency and private-sector expertise and shares with its federal partners a commitment to promoting harmonization and alignment across programs, settings, and payers.

CMS will solicit input from stakeholders through the ongoing Call for Measures[iv] to fill gaps by developing additional measures for MIPS with the funding provided in MACRA. CMS will use the rulemaking process to finalize an initial set of measures for the program that will be made public by November 1 each year. Updates to the MDP, which will be released annually or otherwise as appropriate, will prioritize the development of additional quality measures to address identified gaps and other priority areas using MACRA funding.[v]

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[i] Section 1848(s)(1)(A)
[ii] Section 1848(s)(1)(F)
[iii] Section 1848(s)(1(A), (5)
[iv] Section 1848(q)(2)(D)(ii)
[v] Section 1848(s)(6)

Merit-Based Incentive Payment System

Beginning in 2019,[vi] CMS will apply a positive, negative, or neutral payment adjustment, in a budget-neutral manner, to each MIPS eligible clinician based on a composite performance score across four performance categories[vii]:

- Quality
- Resource use
- Clinical practice improvement activities
- Advancing care information (defined in MACRA as meaningful use of certified electronic health record [EHR] technology)

Measures for use in the quality performance category[viii] are a specific focus of the MDP. CMS will use separate rulemaking cycles to select measures for MIPS and establish criteria for the performance categories. Broadly, MIPS will build upon existing quality measure sets from the Physician Quality Reporting System (PQRS), Value-based Payment Modifier (VM), and Medicare EHR Incentive Program for Eligible Professionals.

In referencing MIPS program participants, this plan substitutes the term "MIPS eligible clinician" for "MIPS eligible professional" as the latter term is defined at section 1848(q)(1)(C) and used throughout section 1848(q) of the Act. No legal or operational impact is intended to result from the change in terms.

To fill identified measure and performance gap areas, CMS will expand and enhance existing measures to promote alignment and harmonization in the selection of measures and specifications, while concurrently collaborating with stakeholders to develop new (*de novo*) measures according to priorities described in Section III (Operational Requirements of the Quality Measure Development Plan).

To accelerate the alignment of quality measurement and program policies, MACRA sunsets payment adjustments for PQRS, VM, and the EHR Incentive Program at the end of 2018 and establishes MIPS beginning January 1, 2019.

Alternative Payment Models

MACRA establishes incentive payments for clinicians who are qualifying participants in advanced APMs.[ix] Advanced APMs must tie payment to quality measures comparable to the quality measures used in MIPS; therefore applicability of candidate measures to support a variety of future APMs[x] is an important element of this MDP.

[vi] Section 1848(q)(1)(B), (q)(6)(A)
[vii] Section 1848(q)(2)(A), (q)(5)(A)
[viii] Section 1848(s)(1)(A), (5)(A)
[ix] Section 1833(z)(1)(A)
[x] Section 1848(s)(1)(A), (5)(B)

Measure Development Timeline

Key milestones and processes mandated in MACRA (shown in green in Figure 1), in conjunction with the pre-rulemaking process (shown in orange) and federal rulemaking cycle for MIPS (shown in blue), anchor the time frame available for measure development. Updates to the MDP will be published annually or otherwise as appropriate.[xi]

Figure 1: Key Dates in the Measure Development Plan
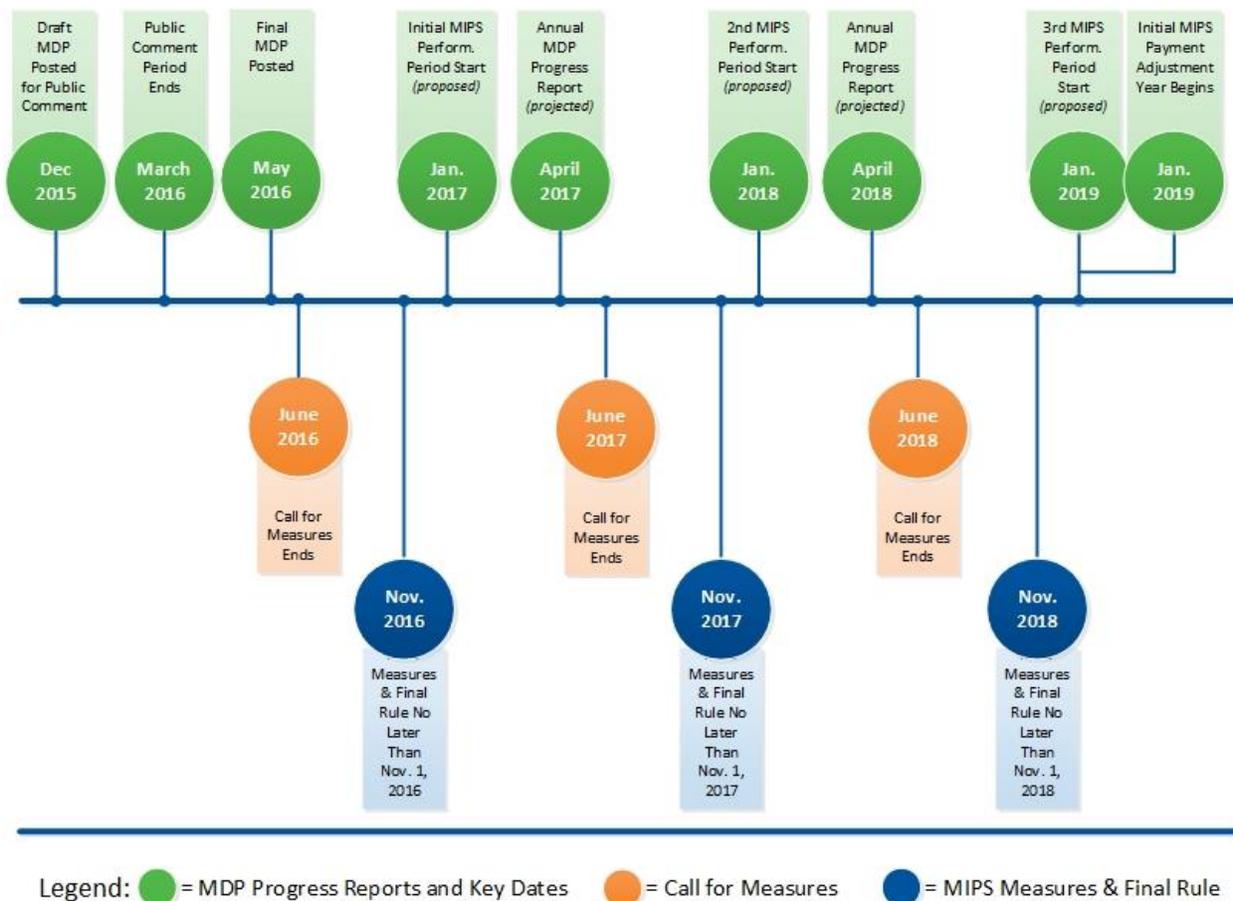
[xi] Section 1848(s)(1)(F)

Operational Requirements of MACRA

Section III (Operational Requirements of the Quality Measure Development Plan) describes the requirements of MACRA pertaining to this MDP and details a strategic approach to each of the following:

Multi-Payer Applicability

Overview – MACRA requires consideration of how to incorporate measures used by private payers and integrated delivery systems within Medicare quality reporting programs.[xii] The creation and use of measures applicable across payers can lessen provider burden and contribute to improved health outcomes by improving data capture and reducing measure variation.

Strategic Approach – CMS will leverage the Measure Applications Partnership (MAP), the Core Quality Measures Collaborative, the Health Care Payment Learning and Action Network, and other multi-stakeholder groups to identify creative solutions for the use of measures across multiple payers and delivery systems from both the private and public sectors to streamline clinician reporting.

Coordination and Sharing Across Measure Developers

Overview – Measure developers are required, to the extent possible, to coordinate across CMS programs, as well as with initiatives in other public programs and in the private sector,[xiii] to seek alignment of related measures and promote broader efficiency and consistency in measure development processes.

Strategic Approach – CMS will eliminate inefficiencies in the measure development process through the application of process improvements (e.g., the use of Lean principles), build upon the successful foundation of collaboration across measure developers and broaden stakeholder participation, and implement new ways to foster communication and knowledge sharing. CMS coordinates measure development efforts across federal agencies through the HHS Measure Policy Council. With the Office of the National Coordinator for Health Information Technology (ONC), CMS also jointly hosts an interagency forum for electronic clinical quality measure (eCQM) developers and stewards, known as the eCQM Governance Group. The National Quality Forum (NQF) routinely convenes developers through monthly conference calls and webinars to promote knowledge sharing, efficiency, and consistency across CMS measure development efforts.

Clinical Practice Guidelines

Overview – MACRA requires the MDP to take into account how clinical practice guidelines and best practices can be used in the development of quality measures.[xiv]

[xii] Section 1848(s)(1)(A)(i)
[xiii] Section 1848(s)(1)(A)(ii)
[xiv] Section 1848(s)(1)(A)(iii)

Strategic Approach – CMS requires measure developers to conduct a thorough review and evaluation of clinical practice guidelines and will promote alignment between the clinical guideline update process and measure maintenance. CMS publishes standards for interpretation of evidence-grading methodologies and selection of clinical practice guidelines through the CMS Measures Management System (MMS) Blueprint.

Evidence Base for Non-Endorsed Measures

Overview – MACRA authorizes CMS to include measures for MIPS that are not consensus-endorsed. Any measure selected for inclusion in MIPS that is not endorsed by a consensus-based entity must have a focus that is evidence-based.[xv] The law also requires CMS to submit a new measure and supporting evidence to a specialty-appropriate, peer-reviewed journal prior to including the measure in a final list of measures to be used in MIPS.[xvi] Existing quality measures[xvii] and measures originating from qualified clinical data registries (QCDRs)[xviii] are exempt from journal requirements.

Strategic Approach – CMS will ensure an evidence-based focus by evaluating new measures throughout the development process, using established criteria with expert review and public comment. CMS will submit the required measure information to appropriate medical journals.

Gap Analysis

Overview – Consideration of gap analyses conducted by the MAP for the NQF, or by other organizations,[xix] is an important factor in the MDP. As the MDP evolves through subsequent updates, CMS intends to enhance the number and utility of reportable clinical quality measures relevant to all specialties (and thereby all MIPS eligible clinicians) for scoring under the MIPS quality performance category. Consistent with the statutory requirement to emphasize outcome measures, CMS intends to particularly focus on gaps in the availability of outcome measures, including patient-reported outcome measures, for specialties.

Strategic Approach – CMS will take a leadership role in collaborating with stakeholders and will conduct analyses of the existing measure portfolio to address gaps in measure domains (e.g., patient safety, care coordination, affordable care) where there is demonstrable variation in performance by clinicians; gaps in types of measures applicable to medical specialties, with a particular focus on outcome measures; measure gaps for non-physician clinicians and clinicians in settings outside of traditional health care sites, including home care and telehealth; and gaps in measures applicable to people with certain health conditions. CMS will guide prioritization of measures to balance narrowly focused specialty-relevant measures with cross-cutting measures that are more broadly applicable. CMS envisions prioritizing the development of measures based on the initial summary of gaps and priorities discussed in Section V (Summary of Gaps and Priorities).

[xv] Section 1848(q)(2)(D)(v)
[xvi] Section 1848(q)(2)(D)(iv)
[xvii] Section 1848(q)(2)(D)(vii)
[xviii] Section 1848(q)(2)(D)(vi)
[xix] Section 1848(s)(1)(C)(i)

Quality Domains and Priorities

Overview – MACRA identifies five quality domains (i.e., clinical care; safety; care coordination; patient and caregiver experience; population health and prevention)[xx] for measures developed under the MDP, which align with the National Quality Strategy and the CMS Quality Strategy.[4] CMS is also taking into consideration the quality domain of affordable care. MACRA further establishes priorities for the types of measures to be developed, which shall include outcome, patient experience, care coordination, and measures of appropriate use of services, such as measures of overuse of clinical procedures.

Strategic Approach – CMS will collaborate with a broad group of stakeholder organizations and persons to develop measures that are important to both patients and clinicians and that represent important performance gaps in the targeted quality domains. CMS has identified initial priorities for each of the domains through input from multi-stakeholder groups (e.g., the MAP), stakeholder input from public comment on the draft plan, and analysis of the PQRS preferred measure sets by specialty. Key priority topics include shared decision-making and personal preferences, misdiagnosis and diagnostic accuracy, medication safety, team-based care, clinical outcomes, and early detection of chronic disease. In addition, CMS has prioritized addressing specialties and professionals with a limited number of applicable measures (e.g., orthopedic surgery, palliative care, pathology, radiology, mental health and substance use, oncology).

Applicability of Measures Across Health Care Settings

Overview – MACRA requires the MDP to consider applicability across health care settings[xxi] in developing quality measures for MIPS and advanced APMs. The law also requires quality measures used in APMs to be comparable to the quality measures used in MIPS.

Strategic Approach – CMS will consider recommendations from recent publications and gather stakeholder input related to measures that are applicable across settings of care and types of clinicians. Options may include adapting specifications for measures developed for a different setting or level of care, using measures that may not be specific to a care setting, and evaluating appropriate attribution of facility-level measures to MIPS eligible clinicians.

Clinical Practice Improvement Activities

Overview – To identify existing gaps and support future measure development, MACRA requires the Secretary to consider clinical practice improvement activities among the four MIPS performance categories in at least the following subcategories: expanded practice access; population management; care coordination; beneficiary engagement; patient safety and practice assessment; and participation in an APM (as defined in section 1833(z)(3)(C) of the Act).[xxii] CMS will consider clinical practice improvement activities in future updates to the MDP.

Strategic Approach – Clinical practice improvement activities (CPIAs) have not yet been established under MIPS. CMS expects these to evolve through the initial MIPS rulemaking

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[xx] Section 1848(s)(1)(D)
[xxi] Section 1848(s)(1)(C)(ii)
[xxii] Section 1848(s)(1)(C)(iii)

process and annual cycles thereafter. As MIPS eligible clinicians begin to identify and submit CPIAs, CMS will evaluate activities to identify concepts that could result in innovative approaches to new measure development. CMS is considering whether participation in evolving initiatives such as the National Testing Collaborative (NTC) could be applied toward the CPIA performance category score.

Consideration for Electronic Specifications

Overview – MACRA encourages the use of certified EHR technologies and QCDRs for reporting quality measures.[xxiii] Measures developed from electronic data sources such as EHRs and other sources, including QCDRs, draw from a rich set of clinical data and can reduce data collection and reporting burden while providing the opportunity to support more timely performance feedback to clinicians than is possible through traditional claims or paper submission mechanisms.

Strategic Approach – In collaboration with ONC, CMS prioritizes eCQM development in a manner that ensures relevance to the public, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. CMS is championing electronic measure development in the core areas of standards, tools, and processes and completing foundational work that is critical for the creation of electronic measures. CMS has commissioned the NQF to conduct research on aligning measure specifications and improving the compatibility of the associated clinical codes.

Key Considerations in Quality Measure Development

Based on extensive experience in quality measure development, CMS has identified key considerations for implementing the MDP, including:
- Partnering with patients, caregivers, and communities in the measure development process.
- Partnering with frontline clinicians and professional societies.
- Aligning measures across payers.
- Reducing clinician burden of data collection for measure reporting.
- Shortening the time frame for measure development.
- Streamlining data acquisition for measure testing.
- Identifying and developing meaningful outcome measures.
- Developing patient-reported outcome measures (PROMs) and appropriate use measures.
- Developing measures that promote shared accountability across settings and clinicians.

Strategic Approach – CMS will implement collaborative approaches to address these challenges:
- Integrating the unique perspective and expertise of the person, family, and/or caregiver in the measure development process.
- Aligning measures conceptually and developing core measure sets across payers and programs, building on efforts such as the Core Quality Measures Collaborative.

[xxiii] Section 1848(q)(5)(B)(ii)

- Deriving measure construction from primary assessment of clinical workflow.
- Prioritizing the development of measures based on data from EHRs.
- Promoting the adoption of process improvements (e.g., Lean principles) to reduce waste throughout the measure development process.
- Using crowdsourcing and outreach, in addition to established forums for knowledge sharing, to engage broader feedback from the developer, clinician, and implementer communities in the measure development process.
- Defining common data elements for shared use across programs and measures.
- Leveraging broader data sources for measure development and promoting the formation of a National Testing Collaborative to facilitate measure testing.
- Prioritizing the development of outcomes measures, including PROMs, and appropriately risk-adjusting outcome measures.
- Supporting exchange of health information to facilitate development of more care coordination and shared accountability measures.

Strategic Vision of the Measure Development Plan

This MDP puts forth a strategic vision and operational approach to fulfill the requirements of section 102 of MACRA. The plan leverages existing CMS measurement strategies, policies, and principles to support the implementation of MIPS and APMs. CMS will ensure that measure developers integrate the goals and aims of the CMS Quality Strategy and other CMS foundational principles into the development of measures with funding provided in section 102 of MACRA.

CMS is striving to produce a person-centered measure portfolio that addresses critical measure gaps and facilitates alignment across federal, state, and private programs. Measures developed under this plan will hold individual clinicians and group practices accountable for care and promote shared accountability across multiple providers.

CMS is committed to reducing clinician burden through the use of measures aligned across federal and private-payer quality reporting programs. Incorporating the voices of patients and consumers throughout the measure development process will ensure that the measures will yield publicly reported results that people can use to make informed decisions about their health care.

The resulting portfolio will reflect key CMS priorities and include person-centered measures that:

- Follow the patient across the continuum of care for populations with one or more chronic conditions.
- Emphasize the therapeutic relationships between the clinician, patient, and family caregiver while recognizing personal and family choice and individual goals for treatment.
- Support improved integration of physical and behavioral health for individuals with substance use and mental health conditions associated with increased risk of other chronic disease.
- Emphasize outcomes, including global outcome measures and population-based measures, balanced with process measures that are strongly tied to outcomes.

- Address patient experience, care coordination, and appropriate use (e.g., overuse and underuse of clinical procedures).
- Promote multiple levels of accountability (e.g., individual clinicians, group practices, system level, population level).
- Include clinically relevant measures for all specialties/subspecialties and all MIPS eligible clinicians that do not currently have clinically relevant measures.
- Apply to multiple types of clinicians, including clinical specialists, non-physician professionals, and non–patient facing professionals.
- Are adopted from other health care settings (e.g., hospitals, nursing homes) and applicable to physicians and other professionals.
- Use data generated from EHRs, based as much as possible on existing workflows during the provision of clinical care.
- Incorporate broader use of QCDRs.
- Can produce results stratified by age, sex, race, ethnicity, and other demographic variables that are available to enable clinicians to eliminate and reduce disparities among vulnerable populations.
- Are suitable for public reporting on the CMS Physician Compare website.[xxiv]
- Account for the variation and diversity of payment models.
- Align with other models and reporting systems—including with Medicaid, other federal partners, and the private sector—and are specified for multi-payer applicability.
- Are appropriate for low-volume clinicians (e.g., rural providers, small and independently owned physician practices).

The evolution and success of this plan will depend on partnering with patients, caregivers, frontline clinicians, professional societies, payers and other stakeholders, and across federal agencies, to shift the focus of our national health care system to paying clinicians and other providers based on value rather than volume.

Summary of Priorities and Gaps

CMS has identified initial priorities for each of the quality domains through input from multi-stakeholder groups (e.g., the MAP), recent publications (e.g., *Vital Signs: Core Metrics for Health and Health Care Progress* report from the Institute of Medicine [IOM]), federal reports and initiatives (e.g., HHS *National Action Plan on Adverse Drug Event Prevention, Core Quality Measures Collaborative*), stakeholder input from public comment on the draft plan, and preliminary analysis of the preferred measure sets identified by specialty within the PQRS program (i.e., measures determined to be most relevant to a particular scope of clinical practice). Initial priority areas are highlighted below, with additional detail provided in Section V (Summary of Priorities and Gaps). Through ongoing collaboration with stakeholders, and during the rulemaking process, CMS may identify additional priority topics and gaps; therefore this list will be continually refined.

[xxiv] Section 1848(q)(9)(A)(i)

Initial Priorities for Measure Development by Quality Domain

Clinical Care

- Measures incorporating patient preferences and shared decision-making
- Cross-cutting measures that may apply to more than one specialty
- Focused measures for specialties that have clear gaps
- Outcome measures

Safety

- Measures of diagnostic accuracy
- Medication safety related to important drug classes

Care Coordination

- Assessing team-based care (e.g., timely exchange of clinical information)
- Effective use of new technologies, such as telehealth

Patient and Caregiver Experience

- Patient-reported outcome measures (PROMs)
- Additional topics that are important to patients and families/caregivers (e.g., knowledge, skill, and confidence for self-management)

Population Health and Prevention

- Developing or adapting outcome measures at a population level, such as a community or other identified population, to assess the effectiveness of the health promotion and preventive services delivered by professionals
- IOM *Vital Signs* topics (e.g., life expectancy, well-being, addictive behavior)
- Detection or prevention of chronic disease (e.g., chronic kidney disease)

Affordable Care

- Overuse measures (e.g., overuse of clinical tests/procedures)

I. Introduction

MACRA[xxv] requires that the Secretary of Health and Human Services develop and post on the CMS website "a draft plan for the development of quality measures" by January 1, 2016, for application under the applicable provisions related to MIPS and to eligible Medicare APMs.[2,3] To meet the requirements of the statute and serve as a strategic framework for the future of clinician quality measure development to support MIPS and advanced APMs, CMS posted the draft Measure Development Plan (MDP) on December 18, 2015; a public comment period followed through March 1, 2016. CMS received input from many stakeholders, including specialty societies and associations, health care providers and clinicians, payers, measure developers, health information technology (IT) developers, clinical registries, and consumers. This final MDP incorporates key themes and specific recommendations identified during review of the public comment.

Additional updates will be posted to the CMS.gov website annually or as otherwise appropriate[xxvi] and will be based on multi-stakeholder collaboration in measure identification, selection, and development processes. CMS intends to continue to seek stakeholder input through a combination of public comment on the initial MIPS rulemaking process and broader collaboration with patients and specialty societies in initiatives such as the MAP, Core Quality Measures Collaborative, and others. CMS will explore new strategies to partner with as many physician and stakeholder organizations as possible. Through this collaboration, CMS will identify those measures and measure gap areas most meaningful to patients, specialists, and subspecialists for measure refinement or development for subsequent inclusion in MIPS and APMs.

Measure Development Plan Purpose

The purpose of the MDP is to meet the requirements of the statute[xxvii] and provide the strategic framework, vision, and expectations for measures to address the quality performance category within MIPS. Initially, CMS is building on the set of clinician quality measures used in current quality reporting and payment programs. Simultaneously, CMS is soliciting new measures to fill the measure and performance gaps through the Call for Measures and supporting the development of new (*de novo*) measures when appropriate. The resulting measure portfolio will prioritize outcomes and relevant measures for specialty clinicians, and will include core measure sets to promote multi-payer applicability and accountability, while further progressing measure alignment. As selected measures are expanded and enhanced and new measures are identified, CMS is committed to retiring existing measures that do not add value for clinicians or patients, such as measures that are topped out (i.e., allow little room for improvement because most clinicians already perform highly), weakly correlate with health outcomes, or are no longer clinically relevant due to new advances in medical treatment.

[xxv] Section 1848(s)(1(A), (5)
[xxvi] Section 1848(s)(1)(F)
[xxvii] Section 1848(s)(1), (5)

CMS is committed to working collaboratively with federal and state partners and private payers to create a set of aligned measures that will reduce clinician burden. CMS also intends to solicit additional input from specialty societies and other stakeholders through public comment on the 2016 notice of proposed rulemaking (NPRM) for section 101 of MACRA[5] to finalize an initial set of measures for the program. Ongoing discussions with professional societies and other stakeholders will also guide the prioritization and development of quality measures in identified gap areas and other priority areas.

Background

As the largest health care payer in the United States with more than 100 million consumers, CMS is at the forefront of our nation's health care delivery system. Building on the principles and foundation of the Affordable Care Act,[6] the Administration, in 2015, announced a clear timeline for targeting 30 percent of Medicare payments tied to quality or value through alternative payment models by the end of 2016 and 50 percent by the end of 2018.[7] As of January 2016, CMS estimated that the agency had achieved the initial goal: Approximately 30 percent of Medicare payments are now tied to alternative payment models that reward the quality of care over the quantity of services provided to beneficiaries.[8]

Figure 2: CMS Quality Strategy Aims

The passage of MACRA supports this transition and establishes an incentive payment system for rewarding high-value care. MACRA provides both a mandate and an opportunity for CMS to leverage quality measure development as a key driver to further the aims of the CMS Quality Strategy (Figure 2)[4]:

- Better Care
- Smarter Spending
- Healthier People

Evolution of CMS Clinician Quality Reporting Programs

To fulfill the measure development requirements of MACRA, CMS will draw on extensive experience and lessons learned in the development and use of quality measures from existing Medicare quality measurement and reporting programs, including the PQRS, VM, and Medicare EHR Incentive Program for Eligible Professionals. Each of these three programs is summarized below.

Physician Quality Reporting System

In 2006, CMS launched the Medicare Physician Voluntary Reporting Program as an initial step to introduce quality reporting and advance measurement in physician and other clinician practices.[9] The program created incentives for voluntary reporting of quality measures and was

implemented in 2007 as the Physician Quality Reporting Initiative, which evolved by 2010 into the Physician Quality Reporting System (PQRS).[xxviii]

From 2007 to 2014, eligible professionals participating in PQRS had the opportunity to earn an incentive payment by satisfactorily reporting data on measures chosen from a designated set of Medicare quality measures or by satisfactorily participating in QCDRs. Beginning in 2015, incentives were replaced with negative payment adjustments for individuals and groups that do not satisfactorily report data on quality measures or satisfactorily participate in QCDRs.

Value Modifier

The Affordable Care Act, section 3007,[xxix] mandated that CMS, beginning in 2015, apply an adjustment that provides for differential payments for items and services under the Medicare Physician Fee Schedule, based on performance (quality of care furnished compared with the cost of care); for 2015, CMS implemented this requirement for physician groups of 100 or more. In 2016, the VM is being further phased in by applying a payment adjustment to groups of physicians with 10 or more eligible professionals. Beginning in 2017, the VM will apply to all physicians and groups of physicians.

Meaningful Use and Electronic Health Records

The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA) to promote the adoption and meaningful use of health information technology (IT).[10] The legislation required HHS to establish programs that provide incentive payments to eligible professionals who meaningfully use certified EHR technology, including reporting on clinical quality measures using EHRs. As of 2015, eligible professionals who do not meet the requirements of the EHR Incentive Program and who do not qualify for a hardship exception receive a negative payment adjustment under the Medicare Physician Fee Schedule.

PQRS, VM, and Medicare EHR Incentive Program Consolidation

The PQRS, VM, and Medicare EHR Incentive Program have each played an important role in the early development of clinician-based quality measurement and reporting in the Medicare program. By aligning these programs according to the requirements of MACRA, CMS seeks to streamline requirements and reduce the reporting burden on clinicians.

CMS intends to build upon lessons learned and design a comprehensive MIPS program that is meaningful, understandable, and flexible with a critical focus on transparency, effective communication with stakeholders, and operational feasibility.

To accelerate the alignment of quality measurement program policies and operations, CMS convened a multi-disciplinary, multi-stakeholder group in December 2015 to provide input and perspective on the initial design for MIPS. Virtual workgroup meetings and additional public breakout sessions expanded the dialogue during the 2016 Healthcare Information and Management Systems Society (HIMSS) conference.

[xxviii] Section 101(b) of division B (Medicare Improvements and Extension Act of 2006) of the Tax Relief and Health Care Act (TRHCA).
[xxix] Section 1848(p)(4)(B)(iii) of the Act

Through the early and continued engagement of stakeholders during these planning and design sessions, CMS intends to streamline the timeline and operational processes required to transition to MIPS and the sunsetting of payment adjustments for PQRS, VM, and the Medicare EHR Incentive Program, as mandated by MACRA.

Overview of MACRA Provisions Concerning the Measure Development Plan

MACRA establishes a system to reward high-value care (e.g., high-quality and efficient) under MIPS and provide incentives to clinicians who are qualifying participants in an advanced APM.

Merit-Based Incentive Payment System

MIPS evaluates each MIPS eligible clinician based on a composite performance score across four performance categories[xxx]:

- Quality
- Resource use
- Clinical practice improvement activities
- Advancing care information

The resulting composite performance score[xxxi] is used to determine and apply a payment adjustment, which will begin in 2019, in a budget neutral manner.[xxxii] Measures for use in the quality performance category are a specific focus of the MDP.[xxxiii]

CMS will use the rulemaking process to establish an annual list of MIPS quality measures.[xxxiv] For the initial implementation of MIPS, CMS expects this measure list to draw from public comments received on both the draft MDP and the initial MIPS rulemaking process. CMS intends to make this list public by November 1, 2016, and annually thereafter. This list is expected initially to include, as applicable, selected quality measures from the PQRS, VM, and Medicare EHR Incentive Program.[xxxv] CMS will use the annual Call for Measures to request that relevant eligible professional organizations and other relevant stakeholders identify and submit quality measures to be considered in the annual list of quality measures and to submit updates to the measures on such list.[xxxvi]

In addition, in early to mid-2016, CMS will host two sessions for representatives of the nation's medical professional societies and patient advocacy groups to discuss opportunities for involvement in clinical quality measure development that supports the MACRA legislation. These meetings will include an overview from CMS representatives about the quality measure development priorities for MIPS, as well as an open discussion with participants

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[xxx] Section 1848(q)(2)(A), (q)(5)(A)
[xxxi] Section 1848(q)(5)(A)
[xxxii] Section 1848(q)(1)(B), (q)(6)(A)
[xxxiii] Section 1848(s)(1)(A), (5)(A)
[xxxiv] Section 1848(q)(2)(D)(i)
[xxxv] Section 1848(q)(2)(D)(v), (vii)
[xxxvi] Section 1848(q)(2)(D)(ii)

about their preferred level of involvement and how CMS may be able to support them in their own measure development.

Alternative Payment Models

In addition to establishing MIPS, MACRA provides incentives for clinicians who are qualifying participants in advanced APMs that meet criteria specified in the law.[xxxvii] The law further requires quality measures used in APMs,[xxxviii] which the MDP is required to address,[xxxix] to be comparable to those used in MIPS. As CMS continues to develop and evaluate APMs, the identification and integration of lessons learned, best practices, and viable measures are essential for the transition to APMs. For example, for accountable care organizations (ACOs), CMS understands the need to advance the development of scientifically sound and widely accepted patient attribution and risk-adjustment methodologies to strengthen the credibility of value-based payment models that rely on quality and cost measure evaluation.

CMS intends to evaluate recommendations received during the draft MDP public comment period about team-based care approaches that may be suited for advanced APMs.

Physician Compare

MACRA[xl] requires that performance and participation information under MIPS and advanced APMs be made available for public reporting on the Physician Compare website.[11] The primary goal of Physician Compare is to help Medicare consumers make informed health care decisions. CMS intends to solicit stakeholder input in this areas in a manner similar to the multi-stakeholder approach being used in MIPS operational design sessions.

MACRA Requirements for the Measure Development Plan

Section III (Operational Requirements of the Quality Measurement Development Plan) contains the Measure Development Plan Timeline and a plan for updates of the MDP. Section III also discusses in detail the following MACRA section 102 requirements applicable to the MDP:
- Multi-payer applicability
- Coordination and sharing across measure developers
- Clinical practice guidelines
- Evidence base for non-endorsed measures
- Gap analysis
- Quality domains and priorities
- Applicability of measures across health care settings
- Clinical practice improvement activities
- Considerations for electronic specifications and QCDRs

[xxxvii] Section 1833(z)(1)(A)
[xxxviii] Section 1848(s)(2)(A)
[xxxix] Section 1848(s)(1)(A), (2)(A), (5)(B)
[xl] Section 1848(q)(9)

II.　CMS Strategic Vision – Measure Development Priorities

CMS intends to evaluate and build upon existing quality measure sets to develop a person-centered portfolio of measures that can drive improvement in health outcomes. CMS will expend MACRA funds for measure development that addresses priority gaps—including focused specialty-relevant measures balanced with cross-cutting measures. CMS also will consider future measures that assess the patient's role in personal health and shared decision-making. The resulting portfolio of measures will address critical measure gaps; facilitate alignment across federal, state, and private programs; and promote efficient data collection and population health, while also balancing individual and shared provider accountability. When publicly reported, these measures will help consumers make informed decisions regarding their choice of health care clinician, facility, and services. Additionally, these measures will promote healthy living and assist in better understanding and reducing disparities in health care.

The strategic vision for the MDP draws from the CMS Quality Strategy, the Physician Quality Reporting Programs Strategic Vision, and the MMS Blueprint, as well as CMS General and Technical Principles for measure developers (see Appendix I). The MDP integrates recommendations from recent relevant publications and stakeholders, where applicable, including those received during the public comment period for the draft MDP.

The MDP leverages existing CMS measurement strategies, policies, and principles in conjunction with stakeholder perspective and recommendations to support the implementation of MIPS and APMs. It is critically important for organizations developing measures with funding from section 102 of MACRA to integrate these foundational pillars into the measure development processes.

As the CMS portfolio of measures evolves to support the transformation of the health care payment system, CMS will continue to seek early and frequent input from clinicians, payers, patients, caregivers, and other stakeholders.

CMS Quality Strategy

Building on the framework of the HHS National Quality Strategy (NQS), CMS laid the foundation for all CMS quality initiatives, including measure development. The CMS Quality Strategy, first released in 2013 and updated in 2016, articulates six goals to improve the quality of care in our health care system (Figure 3)[4]:

Figure 3: CMS Quality Strategy Goals
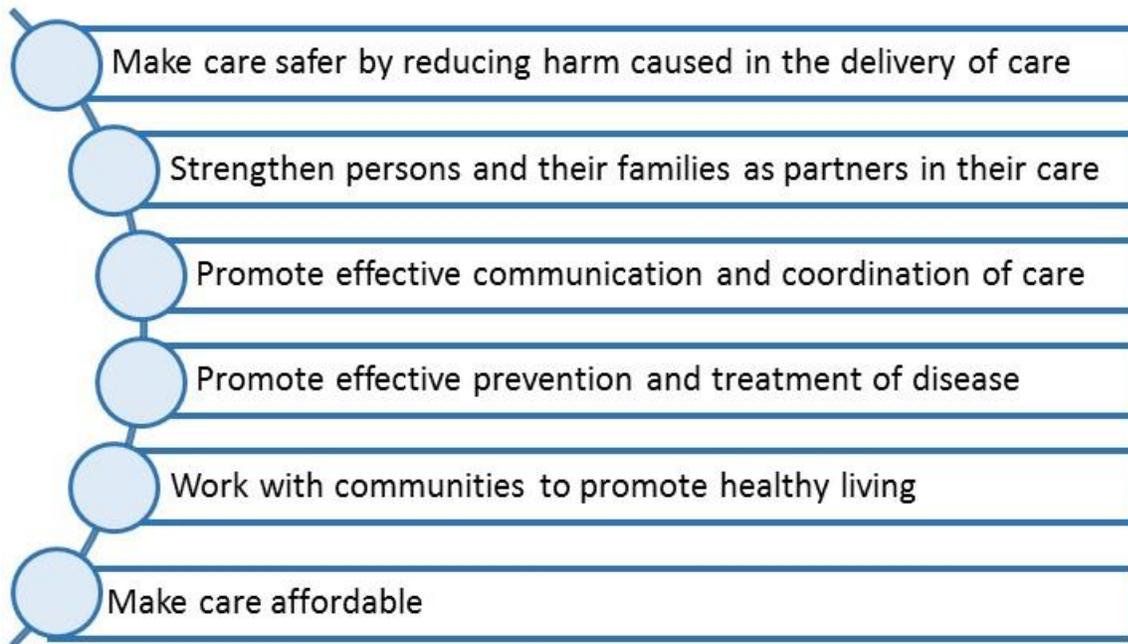
To advance the mission of improving health care outcomes, beneficiary experience of care, and population health while also reducing health care costs, the CMS Quality Strategy identifies four foundational principles that guide actions toward the achievement of these goals[4]:

- Eliminate racial and ethnic disparities to achieve an equitable health care system.
- Strengthen infrastructure and data systems essential to a robust health care system.
- Enable local innovations to allow each community to meet its needs.
- Foster learning organizations to promote learning and education as key parts of quality programs and initiatives.

We intend to require measure developers to fully incorporate the CMS Quality Strategy and explicitly link proposed measure concepts to the goals while addressing the foundational principles.

CMS relies on quality measurement and public reporting as levers to deliver high-quality health care. The MDP describes the approach to build upon and improve existing clinician quality reporting programs and the roles of quality measures in the transition to a value-based health care. Aligning measure development with the goals of the CMS Quality Strategy will result in improved health care quality across the nation.

Physician Quality Reporting Programs Strategic Vision

While the payment adjustments associated with the three existing physician quality reporting programs will sunset under MIPS, the strategic vision of these programs remains applicable to the future value-based payment system. The CMS clinician quality reporting programs play an important role in advancing the goals of the CMS Quality Strategy. The Physician Quality Reporting Programs Strategic Vision describes a long-term outlook for CMS quality

measurement for physicians and other health care professionals and for public reporting programs.[12] It promotes person-centered care and defines an approach to optimizing and aligning quality measurement to support informed decision-making by health care professionals and consumers.

In the Physician Quality Reporting Programs Strategic Vision, CMS noted that five statements define the CMS strategic vision for the future of its quality reporting programs[12]:

- CMS quality reporting programs are guided by input from patients, caregivers, and health care professionals.
- Feedback and data drive rapid cycle quality improvement.
- Public reporting provides meaningful, transparent, and actionable information.
- Quality reporting programs rely on an aligned measure portfolio.
- Quality reporting and value-based purchasing program policies are aligned.

With the passage of MACRA, the strategic vision will bridge the transition from current programs, including PQRS, VM, and the Medicare EHR Incentive Program, into the future state of MIPS and APMs. As part of this transition, CMS will continue to assess, revise, align, and improve current operational processes in ways that eliminate obstacles, streamline reporting, enable interoperability of EHR systems, and minimize administrative burden to clinicians. CMS is accomplishing these objectives through concerted efforts to obtain stakeholder input, including public-private MIPS operational design workgroups (as discussed in Section II [CMS Strategic Vision – Measure Development Priorities]) and focus groups with frontline clinicians across different market areas. From the clinical quality measure perspective, CMS has begun collaborating with specialty societies and associations to identify preferred measure sets in addition to the more generally applicable or cross-cutting measures included in the PQRS system.

CMS Measures Management System

In 2005, CMS introduced the MMS Blueprint as a standardized approach for developing and maintaining quality measures. The approach addressed the need to manage an ever-increasing demand for quality measures in CMS public reporting and quality programs, as well as in value-based purchasing initiatives.

The primary goals of the MMS Blueprint are to provide critical technical information to ensure that measure developers consistently produce high-caliber, person-centered measures that are suitable for consensus review and endorsement, and are developed in a transparent manner with stakeholder input. The MMS Blueprint comprises a set of business processes and decision criteria that CMS-funded measure developers and contractors must follow when developing, implementing, and maintaining quality measures.[13] Specific advice to developers stresses the importance of alignment and harmonization throughout the measure lifecycle and encourages the adoption or adaptation of existing measures when feasible. To ensure broader awareness and use of the MMS Blueprint, CMS will expand education opportunities and outreach to specialty societies, associations, and other measure development organizations.

The MMS Blueprint underscores the commitment of HHS and CMS to coordinate with federal and private partners, and develop strategies to align measures across public programs and

private-sector initiatives. To promote best practices to achieve that objective, CMS makes the MMS Blueprint publicly available on the CMS.gov website as a resource for all measure developers.

The MMS Blueprint is updated at least annually, based on lessons learned and efficiencies gained during the development and implementation of measures.[13] The updates incorporate feedback from key stakeholders (e.g., measure developers, NQF); emerging issues in quality measurement; and innovations in technology and measure development processes, tooling, standards, feedback processes, and testing requirements. CMS will continually streamline the measure development process and strive for better-aligned measures across domains and programs.

The measure evaluation criteria adopted by the MMS Blueprint align with those of NQF:
- Importance to measure and report (evidence, performance gap, and impact)
- Scientific acceptability of measure properties (reliability and validity)
- Feasibility
- Usability and use
- Related and competing measures (harmonization)

Measures recommended for development under MACRA must meet the above evaluation criteria and be regularly maintained to form a sound basis for public reporting and MIPS payment adjustments.

CMS will strive to ensure the availability of carefully evaluated and tested clinical quality measures for use across multiple care settings—a critical objective in the transition from paying for volume to rewarding value.

CMS General and Technical Principles

CMS has identified a number of measure development principles, both general and technical, to guide the development of quality measures (see Appendix I). CMS intends to require organizations that develop measures for MIPS and APMs to embrace these principles in their responses to MACRA procurement solicitations and throughout the measure development cycle.

The General Principles are to be used throughout the measure development process, in particular when identifying concepts for new measures. The Technical Principles will guide the development of measure specifications.

Consideration of Recent Publications and Recommendations

In the development of this MDP, CMS considered recommendations from stakeholders and recent relevant publications, including an IOM report released in 2015, *Vital Signs: Core Metrics for Health and Health Care Progress.*[14] The report identifies a set of standardized measures to enable the health care system to work in a coordinated fashion toward a shared vision of America's health care. The IOM Core Metrics can be used as a roadmap to refine conceptions of measurement and ultimately to redesign the quality measurement system to achieve large-scale results. The IOM report notes that validated quality measures exist for some of the desired

objectives (e.g., childhood immunization rate, patient-clinician communication satisfaction) but not for many others, and that needed measures could be developed under the focus areas of the IOM Core Metrics categories.

CMS shares the IOM vision of an aligned health care system that uses measures across settings, applied at multiple levels of accountability, including global and population health. CMS sees the value and potential of new and existing measures being nested within the broad categories, as appropriate. However, prior to inclusion in MIPS or APMs, continued collaboration and research will be needed to identify the best approaches to carefully construct measures that can be applied at varying levels and with the proper attribution. CMS looks forward to further discussion and partnership with IOM and stakeholders across the public and private sector.

Another recent publication that addresses a topic relevant to this plan is *Performance Measurement for Rural Low Volume Providers*, a final report of the NQF Rural Health Committee.[15] The report recommends phasing in mandatory participation in CMS quality measurement and quality improvement programs by rural clinicians, who face challenges such as geographic isolation, small practice size, and low case volume. The committee suggests mitigation strategies such as reconsideration of exclusions for existing measures and development of new measures that are broadly applicable across rural clinicians, that use continuous rather than binary variables, and that have results expressed as ratios where the numerator is not part of the denominator. Other strategies to be considered, as suggested by stakeholders, include the use of composite measures, use of virtual groups that cluster providers geographically, and a longer data collection timeframe for measurement. CMS will consider the inclusion of rural and low-volume clinicians on measure development technical expert panels, when appropriate.

Measure Integration to Support MIPS and APMs

Through integration of the strategic vision for the MDP into the measure development process, the CMS measure portfolio will evolve to consist of measures that address the goals and aims of the CMS Quality Strategy and the quality domains of clinical care, safety, care coordination, patient and caregiver experience, population health and prevention, and affordable care.

Selected measures from PQRS, VM, and the Medicare EHR Incentive Program will be the starting point for measures to be used in MIPS. To address gaps in that set, MACRA funding will enable the development of new measures that may be used in MIPS and advanced APMs.

The resulting portfolio will reflect CMS priorities and include measures that:

- Follow the patient trajectory across the continuum of care for populations with one or more chronic conditions (e.g., team-based care across the surgical care continuum).
- Emphasize the therapeutic relationship between the clinician, patient, and family caregiver while recognizing personal and family choice and individual goals for treatment.
- Support improved integration of physical and behavioral health for individuals with substance use and mental health conditions associated with increased risk of other chronic disease.
- Emphasize outcomes, including patient-reported outcome measures (PROMs) and measures of functional status; and global outcome and population-based measures, balanced with process measures that are proximal to and strongly tied to outcomes.
- Address patient experience, care coordination, and appropriate use (e.g., overuse and underuse).
- Promote multiple levels of accountability (e.g., individual clinicians, group practices, system-level, population-level).
- Include clinically relevant measures for all specialties/subspecialties and all MIPS eligible clinicians that do not currently have clinically relevant measures.
- Apply to multiple clinicians, including clinical specialists, non-physicians, and non–patient facing professionals.
- Are adopted from other health care settings and are applicable to physicians and other professionals.
- Use data generated from EHRs and claims data, based as much as possible on existing workflows during the routine provision of clinical care.
- Incorporate broader use of additional clinical and sociodemographic data (e.g., qualified clinical data registries).
- Produce measures that are stratified by age, sex,[xli] race, ethnicity, and other available demographic variables to enable clinicians to identify and eliminate disparities among vulnerable populations.
- Are suitable for public reporting on the CMS Physician Compare website.[xlii]
- Account for the variation and diversity of payment models.
- Align with other models and reporting—including with Medicaid, other federal partners and the private sector—and are specified for multi-payer applicability.
- Are appropriate for low-volume clinicians (e.g., rural providers, small and independently owned physician practices).

Incorporating the voices of patients and consumers throughout the measure development process will ensure that the measures are useful to support MIPS and APMs and are meaningful to consumers.

[xli] CMS recognizes that biological sex and gender are both important variables that may affect outcomes. Current data include biological sex. When gender data become available, they may be incorporated for measures that distinguish between sex and gender, such as outcomes associated with issues of gender identity.
[xlii] Section 1848(q)(9)(A)(i)

III. Operational Requirements of the Quality Measure Development Plan

This section describes the proposed operational approach to address the measure-specific requirements of section 102 of MACRA. It includes considerations related to applicability of measures to multiple payers, as well as the need to communicate and coordinate across measure developers. Topics include the use of clinical guidelines, evaluation of the evidence base for quality measures, categorization of measures to the quality domains, and identification of priorities and performance gaps. Other MACRA requirements discussed include consideration for the applicability of measures across settings, the use of clinical practice improvement activities, subcategories to identify concepts for measure development, and the use of electronic specifications for quality measures. Finally, a timeline details the MACRA requirements related to measure development and related pre-rulemaking and rulemaking activities.

MACRA requires CMS to consult with "relevant eligible professional organizations and other relevant stakeholders" for the selection of measures for MIPS,[xliii] and CMS will build upon existing relationships to continue this dialogue. For example, stakeholder groups such as professional organizations, state and national medical societies, clinical registries, and payers (e.g., health plans) are currently engaged in the CMS measure development process. Throughout the transition to MIPS, CMS, and federal partners will focus on broadening engagement of stakeholders and soliciting feedback. In addition to the MDP, CMS released a request for information (RFI) in the fall of 2015 as another means of receiving formal public and stakeholder input related to many of the quality payment program provisions of MACRA, including the quality measure requirements.

This MDP takes into consideration priority areas for future measures for MIPS that CMS identified during the 2015 Measures under Consideration cycle[16]:

> *"MIPS has a priority focus on outcome measures and measures that are relevant for specialty providers. CMS identifies the following domains as high-priority for future measure consideration:*
> > *"1. Person and caregiver-centered Experience and Outcomes*
> > > *"a. CMS wants to specifically focus on patient reported outcome measures (PROMs)*
> > *"2. Communication and Care Coordination*
> > > *"a. Measures addressing coordination of care and treatment with other providers*
> > *"3. Appropriate Use and Resource Use"[xliv]*

[xliii] Section 1848(q)(2)(D)(viii). The statute provides that an "eligible professional organization" means a professional organization as defined by nationally recognized specialty boards of certification or equivalent certification boards. Section 1848(q)(2)(D)(ii)(II)

[xliv] Note: Appropriate use measures are considered in the MDP as part of the quality performance category of MIPS; however, resource use measures are outside of the scope of this MDP.

Incorporating MACRA Requirements

This section addresses nine MACRA requirements relative to the MDP, which are presented as follows: 1) Multi-Payer Applicability of Measures; 2) Coordination and Sharing Across Measure Developers; 3) Clinical Practice Guidelines; 4) Evidence Base for Non-Endorsed Measures; 5) Quality Domains and Priorities; 6) Gap Analysis; 7) Applicability of Measures Across Healthcare Settings; 8) Clinical Practice Improvement Activities; 9) Consideration for Electronic Specifications. A timeline for this MDP that incorporates specific requirements of MACRA is also in this section.

Multi-Payer Applicability of Measures

The MACRA requirement –
> "Under such plan the Secretary shall . . . address how measures used by private payers and integrated delivery systems could be incorporated under Title XVIII."[xlv]

Background – Quality measures currently in use by public and private payers often include more than one measure for the same measure topic, which may be appropriate when the measures are complementary; however, some measures are duplicative and have similar or partially aligned data elements within the technical specifications. The resulting redundancy and variability in measurement create an administrative burden for clinicians and health systems, which often limits opportunity for improving outcomes.

Approach – CMS supports efforts to create core measure sets for clinical specialties that not only are aligned across payers from both the private and public sectors, but also are meaningful to patients and clinicians, represent high-cost conditions, and support a decreased administrative burden and improved quality of care delivery. CMS recognizes that measures require appropriate and valid specification at each level of accountability and emphasizes the importance of conceptual alignment between payers and programs with harmonization or alignment of detailed measure specifications, including data sources, to the extent feasible. Measures should derive data elements from a common set of clearly defined concepts with structured metadata and share logical constructs when possible.

CMS will leverage multi-stakeholder groups to identify the issues related to the development of measures that can be applied across payers and delivery systems. Specific stakeholder groups include the MAP, the Core Quality Measures Collaborative, and the Health Care Payment Learning and Action Network. In addition, CMS will draw upon lessons learned from two ongoing multi-payer collaborative demonstration projects that both providers and payers found successful: the Multi-Payer Advanced Primary Care Program and the Comprehensive Primary Care initiative of the Center for Medicare & Medicaid Innovation.

Measure Applications Partnership

Background – Section 3014(b) of the Affordable Care Act added section 1890A of the Social Security Act, which required that HHS establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use in HHS programs.[6] An important aspect of

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[xlv] Section 1848(s)(1)(A)(i)

the pre-rulemaking process is input on the list of measures under consideration for use in Medicare programs by multi-stakeholder groups convened by the entity with a contract under section 1890 of the Act (currently the NQF). The MAP is the multi-stakeholder partnership convened by the NQF and supports this mandate.

The pre-rulemaking process encourages consensus-building among diverse private- and public-sector stakeholders and provides a coordinated review and discussion of performance measures under consideration across federal programs. Importantly, collaboration between private- and public-sector stakeholders supports a transparent and objective measure review and recommendation process. The MAP seeks public comment immediately upon release by HHS of the list of measures being considered for federal programs each year. The MAP workgroups take these initial public comments into account during the first review of the measures. Later in the review process, the MAP provides a second opportunity for public input on the individual measures and broader measurement guidance for federal programs. The MAP Coordinating Committee considers this public input when producing a final report that includes guidance to the programs.[17] MACRA specifies that the pre-rulemaking process and review by the MAP are optional for measures used for MIPS.[xlvi]

Approach – CMS has received valuable input from the MAP committees, other stakeholders, and the public as part of the MAP review, discussion, and public comment for the measures under consideration. Additionally, in the annual report to CMS, the MAP provides not only recommendations on the prioritization of measures for CMS programs, but also input on key concepts for new measure development to address critical gaps identified during the measure review. The MAP process has completed its fifth pre-rulemaking cycle. CMS will continue to leverage the MAP and its processes for gathering and providing input from stakeholders on measures that will meet the needs of CMS and align with the needs of other payers to support multi-payer applicability of recommended measures.

CMS will work with NQF to promote broad specialty representation on the MAP to ensure that discussions reflect the current practice regarding measures recommended for MIPS. Further, CMS will promote continuous improvement and the application of Lean principles in the MAP processes. Key examples include incorporating opportunities for dialogue with measure developers during the MAP review of measures under consideration, which supports an accurate discussion of measure qualities and potentially shortens the time frame for MAP review and overall measure development.

The Core Quality Measures Collaborative
Background – CMS recognizes the need to build relationships with other payers, physician and other professional groups, and consumer and purchaser representatives to further the alignment of measures. This will result in manageable reporting requirements for providers and measures that are most meaningful to consumers, purchasers, clinicians, and payers as well as a more aligned focus on key areas for quality improvement.

[xlvi] Section 1848(q)(2)(D)(ix)

CMS is active in the Core Quality Measures Collaborative (the Collaborative), a workgroup convened in 2014 by America's Health Insurance Plans (AHIP), a national trade association representing the health insurance industry. The Collaborative currently includes chief medical officers from AHIP member plans; leadership from CMS; and representatives from NQF, consumers and purchasers, and national physician organizations. Input from all stakeholders assists the participating organizations to identify measure gaps and contribute to the focused development of new measures.

Dr. Patrick Conway, Acting Principal Deputy Administrator of CMS and the CMS Chief Medical Officer, stated in a post to the *Health Affairs Blog*:

> "Our goal is to promote a simplified and consistent process across public and private payers by reducing the total number of measures, refining the measures, and relating measures to patient health—known as the 3Rs (reduce, refine, and relate)."[18]

On February 16, 2016, the Collaborative announced the selection of seven core measure sets that will support greater quality improvement and reporting across health care systems.[19] The sets focus on the following areas:

- Accountable Care Organizations, Patient-Centered Medical Homes (PCMHs), and Primary Care
- Cardiology
- Gastroenterology
- HIV and Hepatitis C
- Medical Oncology
- Orthopedics
- Obstetrics and Gynecology

The Collaborative will review these measures sets on an ongoing basis to ensure that they reflect the most up-to-date evidence base as well as the most meaningful measures to the impacted specialties.

Approach – CMS will continue actively participating in the Collaborative and promote the development of other core measure sets for quality reporting programs to support multi-payer applicability. CMS will work to encourage the inclusion of high-priority measures, such as clinical outcome and cross-cutting measures, in core measure sets. CMS also will work to ensure transparency and broad participation of clinician organizations and other stakeholder groups in this Collaborative.

The core measure sets are intended for all payers to use and, over time through the rulemaking process, can become part of the CMS measure portfolio for MIPS and APMs. It is important to note that for quality measures to be included, they must either be endorsed or, if not endorsed, have a focus that is evidence-based. Because many Core Quality Measures Collaborative measures are not yet endorsed, these measures will be required to go through the rulemaking process and be published in the CMS annual list prior to inclusion in MIPS. Core measures will be specified appropriately for individual clinicians, practice teams, health plans, and ACOs, yet

will align in concept to allow for meaningful comparisons. CMS intends to supplement these core sets with other measures to address specialty gaps and the needs of targeted populations.

Health Care Payment Learning and Action Network

Background – The HCPLAN brings HHS, "private payers, providers, employers, states, consumer groups, individual consumers, and other partners together to accelerate the transition to APMs."[20] All stakeholders are invited to participate and leverage the opportunity to join workgroups and learning sessions on increasing the adoption of APMs and other care delivery models.

The workgroups are designed to be short-term, multi-stakeholder initiatives of 10 to 12 experts who will share their experiences and develop a common approach to core issues facing APMs. Workgroups will focus on the specification and alignment of key payment model technical elements, such as quality measures, attribution, risk-adjustment methodology, benchmarking, and data sharing.

Approach – CMS will review and strongly consider strategies and recommendations generated by the HCPLAN workgroups related to quality measures for use in MIPS and APMs. For example, the Clinical Episodes Payment Workgroup released draft recommendations for the design of joint replacement episodes, including quality metrics relevant to joint replacement procedures. As HCPLAN develops further recommendations, CMS will share that information with other partners.

Coordination and Sharing Across Measure Developers

The MACRA requirement –
> "Under such plan the Secretary shall . . . describe how coordination, to the extent possible, will occur across organizations developing such measures."[xlvii]

Background – CMS is intensifying efforts to improve the coordination and sharing of knowledge and best practices among measure developers, across HHS, and with other federal partners. These actions, in concert with stakeholders (e.g., Agency for Healthcare Research and Quality [AHRQ], the Office of the National Coordinator for Health Information Technology [ONC], the Office of the Assistant Secretary for Planning and Evaluation [ASPE]), acknowledge increasing stakeholder demand for measure harmonization and alignment across programs, settings, and payers.

Approach – CMS employs a multi-targeted approach to coordinate measure development. CMS cultivates collaboration internally across operating divisions and with other federal agencies to promote consistency in quality measure development and use of measures in programs in activities such as the following:
- Convening the Quality Measures Technical Forum across CMS divisions to develop recommendations focused on reducing duplication of efforts and eliminating inconsistencies in specifications.

[xlvii] Section 1848(s)(1)(A)(ii)

- Partnering with the AHRQ to co-lead the Measure Policy Council (MPC), composed of representatives from federal agencies.[xlviii] The MPC evaluates measures in use across HHS, creates consensus on aligned core measure sets for high-priority areas, and coordinates future measure development with HHS partner agencies, VA/DoD, and the Office of Personnel Management.

In addition, CMS provides resources to measure developers to facilitate sharing of information and coordination of efforts:

- Collaborating with NQF on monthly NQF measure developer webinars and an annual measure developers meeting.
- Maintaining a comprehensive inventory of measures included in CMS programs, which is publicly available to all stakeholders at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/CMS-Measures-Inventory.html.
- Requiring that measure developers adhere to standard practices identified in the CMS MMS Blueprint, which includes guidance and best practices concerning harmonization and alignment.[13]
- Maintaining a measure developer library where materials created during the measure development process can be shared.
- Hosting information sessions open to all measure developers.
- Supporting the Electronic Clinical Quality Improvement (eCQI) Resource Center, available at: https://ecqi.healthit.gov, which provides a one-stop source for the most current resources to support electronic clinical quality measurement and improvement.[21]
- Integrating lessons learned from measures testing into the eCQI resource center for measure developers to promote knowledge sharing and best practices.

To support the development of clinical quality measures that can be extracted, calculated, and reported from health information technology (IT) systems, CMS established cross-cutting measure development initiatives that actively engage developers and stakeholders in key areas[21]:

- Clinical quality measure process improvement events (e.g., Lean Kaizen), which bring together stakeholders involved in measure development to identify inefficiencies (such as duplicative efforts, waste, and wait) in the development of electronic measures and map out a "future state" for measure development that will produce high-quality measures with few or minimal defects in an abbreviated time frame.
- eCQM Governance Group calls to ensure collaboration, coordination, and communication of key electronic quality measure development, implementation, and reporting decisions for measure developers and stewards involved in development of electronic measures for CMS programs. The group achieves this mission through a

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[xlviii] Other federal agency partners in the MPC include the Administration on Aging (AOA), ASPE, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), National Institutes of Health-National Library of Medicine (NIH-NLM), the Office of Personnel Management (OPM), the Office of the National Coordinator for Health Information Technology (ONC), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

- consensus approach and dissemination of information to stakeholders across CMS and HHS[xlix] and broadly within the health care and health IT industries.
- Biweekly Electronic Measures Issues Group (eMIG) forums and webinars composed of representatives from CMS, measure developers, contractors, health IT developers, and other HHS agencies[l] who serve as subject matter experts to resolve technical issues identified during measure development or early in the implementation process.
- The continuous application of a Web-based Change Review Process to obtain external multi-stakeholder feedback on proposed changes to measure specifications.
- Online feedback mechanisms and forums where stakeholders such as measure developers, stewards, clinicians, and implementers can view and comment on potential errors, misalignments, feasibility, and improvements to existing measures and those under development (e.g., https://jira.oncprojecttracking.org/browse/CQM).

Collectively, these communication channels promote knowledge sharing of best practices, tools, resources, experiences, and individual contractor measure development products. Such initiatives have improved communication and knowledge sharing across measure developers within CMS and HHS and contributed to significantly improved consistency and standardization in clinical quality measure development processes and specifications. CMS will build upon this successful foundation of collaboration and actively seek additional perspective and input from federal departments including Defense (DoD) and Veterans Affairs (VA) in forums such as the HHS Measure Policy Council.

However, CMS understands the need for broader engagement with medical professional societies, associations, and other private-sector and community stakeholders. The nation is best served by fostering collaborative workgroups that bring together a broad range of perspectives— including patients and caregivers—and representation from key stakeholders relative to a specific medical condition, patient population, and/or care delivery setting. Enhancing existing activities and promoting broader engagement are critical to an ongoing and successful partnership among organizations developing measures for MIPS and APMs.

For example, QCDRs currently develop measures for clinical practices, but other measure developers do not always have access to these measures during environmental scan processes. Conversely, QCDRs have not previously had access to CMS claims and enrollment data needed to supplement the clinical data contained within the local registry system and to support empirical analysis and testing activities. Stakeholder comments indicated that QCDRs may not be able to collect demographic information that could aid in identifying disparities. Finally, QCDR measures may not be part of the MAP process and are not required to go through consensus-based endorsement processes; therefore CMS must address any inconsistencies in quality assurance checks and testing of QCDR measures prior to deployment.

To support broader consideration and integration of QCDR measures in MIPS, CMS will promote knowledge and data sharing across measure developers and QCDRs to foster improved

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[xlix] Other federal agency partners in the eCQM Governance Group include AHRQ, CDC, HRSA, NIH-NLM, SAMHSA, and ONC.

[l] Other federal agency partners in eMIG include AHRQ, CDC, HRSA, ONC, and SAMHSA.

consistency and standardization in measure development, while collectively identifying methods to improve QCDR data quality.

Based on public comment feedback, CMS intends to increase awareness of opportunities to participate in important multi-stakeholder initiatives such as the MAP and the Core Quality Measures Collaborative. As part of this process, CMS intends to improve the messaging and visibility of solicitations for technical expert panel (TEP) nominations, calls for public comment on quality measures, and related Web pages.

With the passage of MACRA, this collaborative approach is essential for the sustainability of clinician quality measurement programs. CMS recognizes that the benefits can extend beyond Medicare to advance efforts at creating aligned measures for Medicaid, other federal partners, and private payers.

Clinical Practice Guidelines

The MACRA requirements –
> "Under such plan the Secretary shall . . . take into account how clinical best practices and clinical practice guidelines should be used in the development of quality measures."[li]

> "In selecting measures for development under this subsection, the Secretary shall consider— … clinical practice guidelines to the extent that such guidelines exist." [lii]

Background – The IOM defines clinical practice guidelines as follows:
> "Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[22]

MACRA prioritizes outcome measures, including patient-reported outcomes and measures of patient perception, as well as measurable clinical outcomes. However, process measures such as those based on clinical practice guidelines and strongly associated with outcomes remain an important part of quality measurement.

Evidence-based research provides a foundation for sound clinical practice guidelines and recommendations. While clinical practice guidelines are available for most professions and specialties, it is important to note that these guidelines vary in their development approach, grading of evidence, and frequency of updates. The clinical practice guidelines are a key foundation of the NQF measure evaluation criterion of importance, which process measures must pass to receive NQF endorsement. Therefore measure developers are required to conduct a thorough review of clinical practice guidelines as part of the measure development process.

Because guidelines typically address a single condition, measure developers must take into account certain limitations of that singular focus. Multiple chronic conditions—which affect as

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[li] Section 1848(s)(1)(A)(iii)
[lii] Section 1848(s)(2)(B)(ii)(II)

many as three out of four Americans aged 65 years and older[23]—may require more complex care decisions than guidelines aimed at a single condition adequately address.[24,25] The research studies that inform clinical practice guidelines frequently do not include persons with multiple co morbidities.

An additional consideration in the use of clinical guidelines is the need to align the updates of guidelines and clinical measures. Currently, measure developers conduct maintenance of specifications annually or more frequently and conduct comprehensive evaluations on a 3-year cycle. However, the process of updating clinical guidelines currently varies widely, depending on the topic. During measure maintenance and implementation, measure developers conduct periodic scans to identify whether underlying supporting evidence has changed. If new underlying evidence necessitates a major modification to the measure, the developer will initiate an ad hoc review.

Approach – CMS fully understands the importance of maintaining and updating quality measures through a combination of routine clinical practice guideline review, NQF maintenance cycles, and, for electronic clinical quality measures, annual update processes. Additionally, measure developers and stewards should be cognizant of Medicare covered services when creating or maintaining measure specifications.

Physicians and other clinicians, as agents of the patient, have a central role in health delivery. CMS will ensure that measure developers continue to include members from clinical specialty societies and other health organizations that create clinical practice guidelines in the Call for Technical Expert Panel process, in which their participation is essential to quality measure development. CMS will encourage efforts to synchronize the release of revised measure specifications with publication of the relevant guidelines.

CMS directs measure developers to evaluate clinical practice guidelines as described in the CMS MMS Blueprint.[13] The MMS Blueprint details the methods for identifying (e.g., National Guideline Clearinghouse) and selecting the most appropriate evidence and clinical practice guidelines to support quality measures and provides additional references (e.g., IOM: *Clinical Practice Guidelines We Can Trust*[22]). The level of evidence accepted to support the development of measures may vary depending on the medical specialty and the measurement topic (e.g., patient-reported measures); however, developers shall strive to focus measurement on those areas where the highest level of evidence is available.

To focus explicitly on the need for clinical guideline developers to address multiple chronic conditions, HHS and IOM convened a meeting of expert stakeholders in May 2012 that developed *Multiple Chronic Conditions: A Strategic Framework.*[26] The framework is a set of new and previously identified principles for addressing issues related to multiple chronic conditions in the guideline development process.[27] CMS will continue to work with specialty societies and other guideline developers to provide data addressing multiple chronic conditions.

Evidence Base for Non-Endorsed Measures

The MACRA requirement –
> "… Any measure selected for inclusion in such list that is not endorsed by a consensus-based entity shall have a focus that is evidence-based."[liii]

Background – While MACRA requires that measures selected for use in MIPS be "evidence-based" if not endorsed by a consensus-based entity, the law does not define evidence-based or specify how to evaluate the evidence. The use of a consistent set of criteria for evaluating evidence will ensure that measures developed for use in CMS programs are rooted in strong evidence.

One of the CMS core principles for measure development is that development of the business case for an evidence-based measure concept is the first step in the measure development cycle. The business case is a concise overview of the rationale and evidence supporting the development of a measure. Sections describe how the measure aligns with the CMS Quality Strategy, patient/caregiver perspectives about the measure (if available), impact (e.g., number of persons affected, improved quality of life, lives saved, reduced costs), variations in performance, evidence of a process-outcome link, and feasibility. Review and evaluation of evidence are important components of developing the business case; however, developers also quantify the performance gap or variation in performance to demonstrate that there is room for improvement. Measures that are based on clinical guidelines or other evidence, but for which there is little room for improvement because most clinicians already perform highly (i.e., measures are topped out), are less desirable for inclusion in quality programs.

Approach – CMS plans to use the rating criteria established by NQF to evaluate the quality, quantity, and consistency of the evidence for the development of quality measures included in this plan.[28] Furthermore, unless a measure is targeting a specific subset of patients, it is expected that this evidence will have been informed by a diverse population that represents proportionate numbers of persons by age, sex, race, and ethnicity.

CMS will continue to require that measure developers submit a well-crafted business case that includes a thorough review of the evidence, the extent to which clinician performance varies, and the potential impact of the measure concept (e.g., improved quality of life, improved functional status, lives saved, reduced costs). For measures that are not consensus-endorsed, CMS will ensure that each measure is evidence-based, receives broad stakeholder input, and is evaluated on the basis of the NQF measure evaluation criteria used in the consensus review process (i.e., importance, scientific acceptability, feasibility, and usability). While encouraging organizations to develop innovative measures, CMS will ensure that measures developed for MIPS and APMs are scientifically rigorous and support achievement of the key strategies outlined in the MDP. For example, measure concepts will receive a lower priority for development if there is minimal variation in performance or if a strong evidence base is lacking.

[liii] Section 1848(q)(2)(D)(v)

With the exception of measures developed for QCDRs and existing quality measures, MACRA requires submission of the measure and supporting evidence to a peer-reviewed journal. The opportunity for peer review helps ensure that new measures implemented in MIPS are meaningful and comprehensive. CMS proposes to obtain the required measure information during the Call for Measures. Information sought from measure developers, owners, and stewards for journal submission will include, but is not limited to: background; clinical evidence and data that support the intent of the measure; a recommendation for the measure, which may come from a study or from the U.S. Preventive Services Task Force; and how this measure aligns with the CMS Quality Strategy. CMS will submit the required measure information to appropriate medical journals.

Gap Analysis

The MACRA requirement –
> "In developing the draft plan under this paragraph, the Secretary shall consider . . . gap analyses conducted by the entity with a contract under section 1890(a) or other contractors or entities. . . ."[liv]

Background – This MDP considers gap analyses and recommendations from the MAP with regard to priorities for measure development. The MAP identifies measure gaps related to specific clinical topics and prioritizes areas for measure development. In a 2015 report, the MAP advised CMS to include more high-value measures (e.g., outcomes, patient-reported outcomes, composites, intermediate outcomes, process measures proximal to and strongly tied to outcomes, cost and resource use measures, appropriate use measures, care coordination measures, and measures focused on specialty care, special patient populations, and patient safety) as a critical program objective for clinician quality measurement programs. These objectives establish a framework for the future direction of measurement development.[29] In 2016, the MAP identified additional priorities, including person-centered measures such as patient-reported outcome measures, functional status measures, and measures that incorporate personal values (e.g., preferences for end-of-life care). Measures regarding team-based care also were highlighted.

MACRA requires the Secretary to consider the circumstances of non–patient facing professionals and authorizes the Secretary to apply alternative measures or activities for such professionals. The MAP supported alignment of measures used in other programs and registries and recommended adding outcome measures and clinically relevant measures for specialties/subspecialties that do not currently have clinically relevant measures.[29]

As the MDP evolves through subsequent updates, CMS intends to increase the number of reportable clinical quality measures relevant to all specialties (and thereby all MIPS eligible clinicians) to be scored under the MIPS quality performance category. The PQRS program identifies "preferred" measures for certain specialties (i.e., measures determined to be most relevant to a particular scope of clinical practice, based on discussion between CMS and the related specialty societies). A table in Appendix II provides a preliminary analysis of the preferred measure sets identified by specialty and illustrates gaps for many specialties. For

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[liv] Section 1848(s)(1)(C)(i)

example, dermatology, emergency medicine, hospitalists, mental health, oncology, pathology, radiology, and urology each have fewer than 10 measures. Additionally, measures applicable to some specialties have not been classified into PQRS preferred measure sets; these practice areas include but are not limited to allergy and immunology, anesthesiology, colorectal surgery, medical genetics, neurological surgery, nuclear medicine, orthopedic surgery, otolaryngology, pediatrics, plastic surgery, preventive medicine, palliative care, wound care, and optometry. The relevance of certain measures may depend on the practice type and specialty.

CMS also understands there may be cases in which a specialty has PQRS preferred measure set listed, but additional collaboration is needed to determine whether the measures address gaps in performance or sufficiently apply to the specialists or subspecialists intended to report the measure. CMS will prioritize the development of specialty measure to fill gaps and continue to confer with professional societies in the development of new measures for MIPS and advanced APMs, with a particular emphasis on developing new outcome measures. Initial measure topic priorities are discussed in the Quality Domains and Priorities section.

Approach – The strategic approach for gap analyses related to MIPS and advanced APMs will consider measure gaps in each of the quality domains identified in section 102 of MACRA. Prioritized measure gaps identified by national stakeholders include measures addressing patient safety, care coordination, clinical outcomes, and affordable care. Measure concepts identified to fill these gaps should emphasize person-centered measures, including patient-reported outcomes and functional status measures, measures that incorporate personal preferences and shared-decision making, and team-based care. Measure prioritization should balance narrowly focused specialty-relevant measures with cross-cutting measures that are more broadly applicable.

The areas that the MAP and other stakeholders have identified as gaps in the current set of clinician measures align with the priorities identified in MACRA. CMS will focus on the development of measures in these high-level gap areas that address true gaps in performance by clinicians, where there is demonstrable variation in care and therefore opportunity for improvement. To improve measure coverage for all MIPS eligible clinicians, CMS intends to evaluate gaps in measures for specialties and subspecialties, as reporting ability can vary significantly for different types of clinicians.

Although the lack of measures for many specialties makes those fields a priority for measure development, CMS will also consider the needs of primary care clinicians, particularly related to cross-cutting concepts of care coordination and continuity.

For transparency and to promote knowledge sharing among measure developers, CMS will publish and update, as appropriate, any gap analyses prepared for MIPS.

Quality Domains and Priorities

The MACRA requirements –

"QUALITY DOMAINS.—For purposes of [section 1848(s) of the Act], the term 'quality domains' means at least the following domains[lv]:

"(i) Clinical care.

"(ii) Safety.

''(iii) Care coordination.

''(iv) Patient and caregiver experience.

''(v) Population health and prevention."

"In developing the draft plan under [section 1848(s)(1) of the Act], the Secretary shall give priority to the following types of measures[lvi]:

''(i) Outcome measures, including patient-reported outcome and functional status measures.

''(ii) Patient experience measures.

''(iii) Care coordination measures.

''(iv) Measures of appropriate use of services, including measures of over use."

Background – The quality domains mandated for use in MIPS align with the NQS priority areas and CMS Quality Strategy goals. CMS strives to clearly align quality measures with these domains to address gaps, drive quality improvement, and ensure the CMS Quality Strategy goals are achieved.

In 2013, to facilitate and support a broad understanding of how quality measures can monitor progress on the NQS, HHS in partnership with the NQF generated a comprehensive set of decision rules for federal agencies and measure developers to apply when assigning new and existing quality measures to the six domains of the National Quality Strategy. The *HHS Decision Rules for Categorizing Measures of Health, Health Care Quality, and Health Care Affordability* (also known as the HHS Decision Rules) standardize the application and interpretation of NQS priorities and assignment of measures to domains to carefully identify measure gaps and priorities for new measure development.[30] CMS recognizes that measures may apply to more than one domain.

Through the use, evaluation, and maintenance of the HHS Decision Rules, CMS intends to improve coordination of new measure development, promote harmonization of existing measures, provide insight toward achieving a set of highly effective measures that minimizes measurement burden and provides stakeholders with useful information on health and health care when measures are publicly reported.

It should be noted that some overuse measures are categorized in the safety domain, as overuse of some services has a strong association with patient harm. MACRA requires measures of "appropriate use of services, including measures of over use," and these measures have sometimes been previously classified for the PQRS program in the efficiency and cost reduction quality domain (or the safety domain, as noted above). CMS therefore proposes to include affordable care as a quality domain in addition to the five quality domains identified in MACRA

[lv] Section 1848(s)(1)(B)

[lvi] Section 1848(s)(1)(D)

(clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention).[lvii]

Additionally, MACRA prioritizes outcome measures, patient experience measures, care coordination measures, and measures of appropriate use of services, such as measures of overuse.

Based on the review of available measures by specialty type, stakeholder input, and recommendations from the MAP, priorities and opportunities for measure development and selection of these measure types within each quality domain are addressed below.

Clinical Care

Background – Clinical care measures reflect clinical care processes closely linked to outcomes, based on evidence and practice guidelines from professional clinical societies, or can be measures of person-centered outcomes of disease conditions, including PROMs and measures of functional status (topics that MACRA has prioritized). Appropriate use measures (e.g., underuse measures such as *NQF 0067: Coronary Artery Disease (CAD) – Antiplatelet Therapy*) can also be assigned to this domain.

Approach – CMS will collaborate with specialty groups and associations to develop measures for which there are important gaps in performance and on topics that are important to both patients and clinicians. Outcome measures (including PROMs and measures of functional status), intermediate outcome measures or process measures strongly tied to outcomes, and measures assessing diagnostic skills and adherence to clinical practice guidelines are measure development priorities for MIPS and advanced APMs.

For clinical care measures, CMS has identified key measure topics as priorities, including but not limited to the following:

- Measures incorporating personal preferences and shared decision making (e.g., measures of palliative or end-of-life care and recovery-oriented care for behavioral health).
- Cross-cutting measures that may apply to more than one specialty (e.g., biopsy measures that might be applicable to dermatology, pathology, and oncology).
- Focused measures for specialties that have clear gaps with fewer than 10 PQRS preferred measures (i.e., dermatology, emergency medicine, hospitalists, mental health, oncology, pathology, urology, radiology) and specialties for which PQRS preferred measure sets have not yet been developed, including but not limited to allergy and immunology, anesthesiology, colorectal surgery, medical genetics, neurological surgery, nuclear medicine, orthopedic surgery, otolaryngology, pediatrics, plastic surgery, preventive medicine, palliative care, wound care, and optometry.

CMS acknowledges that many specialties and subspecialties will require development of focused measures that are applicable to the specialty care provided. Each clinical specialty will be reviewed carefully for measurement gaps and opportunities.

[lvii] Section 1848(s)(1)(B)

Safety

Background – Safety measures reflect the safe delivery of clinical services in all health care settings. These measures address a structure or process that is designed to reduce risk of harm or the occurrence of an untoward outcome in the delivery of health care, such as an adverse event. Safety measures also address complications of procedures, treatments, or similar interventions during health care delivery. Measures of inappropriate use that could harm a patient (e.g., *NQF 0022: Use of High Risk Medications in the Elderly*) are also included in this domain.

In addition, outcome measures that address complications or other harm caused by the health care system or a health care provider (e.g., *HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate*, *NQF 0564: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures*) are in this domain. Although safety has been a recent focus of quality measurement and health care improvement activities in the hospital setting, gaps in physician-level safety measures persist. For example, the NQF Quality Positioning System, a comprehensive searchable online database of endorsed measures, identified 18 out of 137 NQF-endorsed measures in the safety domain as being applicable to the clinic or office setting.[31] Therefore ample opportunities exist to identify performance gaps and to develop additional measures in the Safety domain.

Approach – CMS will collaborate with stakeholders in the development of safety measures for MIPS eligible clinicians as a high priority in alignment with the goals of the CMS Quality Strategy. Where appropriate, CMS will align new measures with safety measures in other care settings. Measure topics to prioritize include diagnostic accuracy, medication safety, complications from procedures, and all-cause harm in the outpatient, ambulatory setting, or observational status.

Stakeholder organizations representing consumers have highlighted misdiagnosis of disease as a key safety concern and an important new focus for measures of patient safety. Prioritizing these types of measures could also address inclusion of professional societies representing non–patient facing professionals (e.g., radiology, pathology), which have recommended the consideration of measures of diagnostic accuracy. The IOM report on *Improving Diagnosis in Healthcare* suggests establishing a non-punitive culture and monitoring processes such as timely transmission of results between diagnostic professionals and members of the care team responsible for treatment.[32] Furthermore, depending on how the measures are operationalized, effective diagnosis could be considered an outcome measure concept.

Medication safety is another priority for measurement that stakeholders and the MAP have stressed. The HHS *National Action Plan for Adverse Drug Event Prevention* highlights key considerations for measures in the ambulatory setting, focusing on the drug classes that represent the highest risk for patients (i.e., diabetes agents, opioids, and anticoagulants).[33] In particular, in response to the rising epidemic of opioid overprescribing and related overdose in the United States, the CDC has recently issued new guidelines for prescribing opioids for chronic pain.

Care Coordination

Background – Measures assigned to the care coordination domain focus on appropriate and timely sharing of information with patients, caregivers, and families and coordination of services among health professionals. The measures in this domain may also reflect outcomes of successful coordination of care.

Care coordination measures that section 102 identifies as a priority for measure development can promote shared accountability among clinicians contributing to a person's care. For example, a health care team for a person with type 2 diabetes mellitus might include a primary care physician, advanced practice registered nurse, podiatrist, optometrist, endocrinologist, pharmacist, dietitian, and other medical professionals. Measures that reflect communication and sharing of information across the care team (including the patient) are increasingly important not only for MIPS, but also for APMs that promote shared accountability.

Outcome measures that reflect successful care coordination may include measures of admissions and readmissions to the hospital, such as the *Hospital-Wide All-Cause Unplanned Readmission Measure* in the hospital Inpatient Quality Reporting Program*, Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF,* proposed for use in the Inpatient Psychiatric Facility Quality Reporting Program, and the *All-Cause Unplanned Admissions for Patients with Heart Failure* measure used in the Shared Savings Program. These measures are applicable to multiple members of the care team and rely on relationships built at the community level to support the needs of a person moving between clinicians and care settings. Patient-reported outcomes that address the extent to which a person's care was professionally and purposefully organized between two or more clinicians or other providers to facilitate the appropriate delivery of health care services are also in this domain.

Approach – The MIPS performance category of clinical practice improvement activities includes a subcategory of care coordination.[lviii] Through the care coordination subcategory, performance gaps and best practices may be identified, resulting in potential concepts for new measure development. For purposes of clinical practice improvement activities, MACRA provides examples of care coordination activities, including timely communication of test results, timely exchange of clinical information to patients and other clinicians or other providers, and use of remote monitoring and/or telehealth.[lix] Priorities for measure topics related to care coordination focus on assessing team-based care (e.g., timely exchange of clinical information), use of new technologies such as telehealth, and other structural measures of integration and collaboration. Measures also should encompass coordination of care between medical and behavioral health clinicians and facilities.

Team-based care is increasingly recognized by stakeholders and the MAP as an important priority for cross-cutting measurement. To improve collaboration across clinicians, CMS intends to incorporate both primary care and specialist accountability across care settings. For example, the EHR Incentive Program building block measure *PQRS #374: Closing the Referral Loop – Receipt of Specialist Report* evaluates the effectiveness of tracking referrals from the primary

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[lviii] Section 1848(q)(2)(B)(iii)(III)
[lix] Section 1848(q)(2)(B)(iii)(III)

care physician to the specialist. CMS is considering expansion of this measure to include specialist reports to primary care physicians.

Additionally, the ability to link disparate data sources is critical to the development of innovative care coordination quality measures. Therefore CMS promotes the development of measures using hybrid data sources (i.e., more than one data source used to develop a measure) to link information between care settings. Until interoperability is universal, quality reporting systems that aggregate several sources of data may provide the most accurate assessment of quality. For example, measures that link EHR data and claims data, such as *NQF #2732: International Normalized Ratio (INR) Monitoring for Individuals on Warfarin after Hospital Discharge*,[34] support the documentation of appropriate follow-up care provided post-discharge from the hospital setting (i.e., INR lab test is performed within 14 days following discharge for a patient on warfarin).

Patient and Caregiver Experience

Background – The domain of patient and caregiver experience includes measures that focus on the potential to improve person-centered care and family and caregiver experiences. For example, this domain includes measures of organizational structures or processes that foster the inclusion of persons and family members as active members of the health care team and collaborative partners with clinicians and provider organizations. This domain also includes PROMs that assess patient-reported experiences and outcomes that reflect involvement of persons and families in the care process and demonstrate knowledge, skill, and confidence to self-manage health care.

To understand and measure patient and caregiver experience of care, CMS implements patient experience surveys across multiple programs and settings of care. These surveys ask patients (or in some cases, their families or caregivers) about their experiences with health care providers and address topics for which patients are the only or best source of information, such as whether the person was treated respectfully.[35] Many of the CMS patient experience surveys are part of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) family of surveys.[36] Additionally, the Health Outcomes Survey is a PROM used in the Medicare Advantage (MA) program to assess each MA organization's "ability to maintain or improve the physical and mental health functioning of its Medicare beneficiaries."[37]

Approach – PROMs are a key priority for CMS in the development of patient and caregiver experience measures. CMS will continue to develop new patient experience surveys to ensure that these important measures of quality encompass all care settings and providers (e.g., specialists). CMS will also refine existing patient experience surveys based on stakeholder feedback to incorporate additional topics that are important to patients and families/caregivers (e.g., knowledge, skill, and confidence for self-management and whether the provider acted in accordance with the person's preferences; participation of family members in care discussions or electronic communications; accurate documentation of family members who are authorized decision-makers). CMS will explore incorporating an assessment of cultural competency and perspectives of minority and vulnerable populations (e.g., individuals with limited English proficiency, low health literacy, mobility impairments, or other disabilities). CMS will balance the effort to obtain important information with the need to minimize burden to patients and clinicians in implementing and responding to the surveys. To address this need, CMS will evaluate the use of innovative technology for the administration of CAHPS surveys, including

centralized, electronic short-form patient experience surveys. Importantly, this approach could enable the measurement of patient experience at the individual physician level (e.g., through the use of smartphone applications for survey responses) and at less expense.

CMS will encourage the development and use of specialty-specific PROMs for MIPS and APMs. Priority will be given to the development of PROMs for which validated instruments have been developed and used in the clinical setting. CMS will require that PROM development will be informed by clinical experts partnering with patients. For example, the Alliance of Dedicated Cancer Centers is collaborating with the International Consortium for Health Outcomes Measurement to validate PROMs for early-stage prostate cancer and lung cancer. As these PROMs evolve, CMS can evaluate the viability of these measures for inclusion in a specialty-specific measure set in MIPS. CMS also recognizes that new PROM implementation may require a building-block approach in which temporary measures are put in place until further evaluation and validation occurs.

Population Health and Prevention

Background – Population health is defined as *"*the health outcomes of a group of individuals, including the distribution of such outcomes within the group."[38,39] Measures in this domain reflect the use of clinical and preventive services and the achievement of improvements in the health of the population served. Included in this domain are outcome measures that reflect the health of a population or community and process measures that focus on the primary prevention of disease or screening for early detection of disease that is unrelated to a current or prior condition. Examples include *NQF #2020: Adult Smoking Prevalence* and other measure topics such as cancer incidence and prevalence or spread of communicable disease.

Approach – MIPS allows for the use of "global and population based measures" in the quality performance category.[lx] CMS is currently developing population-health based measures and will consider adapting outcome measures at a population level, such as a community or other identified population, to assess the effectiveness of the health promotion and preventive services delivered by professionals. As with other types of outcome measures, these measures would reflect actions of others in a community and could be developed or used in combination with process measures that assess the actions of the individual, facility, or practice. CMS will evaluate closely the attribution methodology of population health measures. Measure specifications will be carefully evaluated for appropriate attribution at different levels of measurement: individual clinician, group, facility, and population.

The IOM *Vital Signs* report contains suggestions for 15 core measures that could be applicable to the population level. Eight of the topics for core measures identified by the IOM fall in this domain and can be considered for measure development: life expectancy, well-being, overweight and obesity, addictive behavior, unintended pregnancy, healthy communities, preventive services, and community engagement. CMS is engaged in collaborative efforts with Healthy People 2020 and with the Centers for Disease Control and Prevention (CDC), which currently reports on topics such as unintended pregnancy and obesity.

[lx] Section 1848(q)(2)(C)(iii)

Recently the IOM convened an ad hoc panel addressing population health measurement with a key objective to "highlight existing and emerging population health metrics sets and explore their purposes, areas of overlap and gaps."[40] CMS will encourage developers to consider these reports in developing measures for the population health domain. Stakeholders noted potential metrics related to the detection or prevention of chronic disease (e.g., chronic kidney disease).

Affordable Care

Background – This domain consists of quality measures that reflect efforts to lower costs, reduce errors, and significantly improve outcomes. These are measures of appropriate use of health care resources or inefficiencies in health care delivery.

Measures of appropriate use of services, including measures of overuse, are identified as a priority for measure development under MACRA. The 2016 PQRS includes 20 measures in this domain out of the 281 measures in the set.[41] Examples of overuse measures in PQRS include *Overutilization of Imaging Studies in Melanoma* and *Use of Imaging Studies for Low Back Pain*. Reduction of unnecessary procedures and services will result in improved health care delivery, safer care, and lower costs for patients and payers. In many cases, measures in the domains of clinical care, patient safety, and population health and prevention assess the appropriate use of services, including underuse. Measures of the delivery of inappropriate care that does not place the person's health at risk (e.g., measures of certain unnecessary imaging or laboratory studies) are categorized in the efficiency and cost reduction quality domain. In cases where the overuse of a procedure or test has the potential to cause patient harm, the measure is categorized as a safety domain measure.[30]

Approach – CMS considers appropriate use measures to be a very high priority for MIPS and APMs. CMS will collaborate closely with stakeholders to consider evidence-based practices related to overuse, such as the appropriate use criteria of some specialty societies. Recommendations by the U.S. Preventive Services Task Force, U.S. Government Accountability Office, and HHS Office of the Inspector General also include topics suitable for the development of appropriate use measures.

The Choosing Wisely® initiative of the American Board of Internal Medicine (ABIM) Foundation aims to reduce inappropriate use of certain tests and procedures to support persons in their efforts to make informed and effective health care decisions. Recommendations for clinicians on the Choosing Wisely website are supported by evidence and developed by specialty societies and organizations. The website includes lists of recommendations for the appropriate use of tests and procedures covering 31 topics submitted by 70 professional organizations.[42] CMS recognizes that the recommendations from this initiative are not absolute and that many of the recommendations are not suitable for measure development. Therefore recommendations will be evaluated carefully for potential suitability for measurement, and specialty organizations responsible for the underlying recommendation will be engaged early in development if any such measures are considered.

As clinicians focus on performance on overuse measures, a potential unintended consequence of quality measurement is underuse of services. As measures are developed for other quality domains, CMS will consider the development of "balancing measures" that can mitigate the potential for unintended consequences.

Applicability of Measures Across Health Care Settings

The MACRA requirement –

> "In developing the draft plan under this paragraph, the Secretary shall consider . . . whether measures are applicable across health care settings."[lxi]

Background – MACRA requires this draft MDP to consider the applicability of measures across health care settings. Applicability of measures across settings can be achieved by:

- Adapting and aligning measures originally developed for another setting or level of the health care system (e.g., health plan) to the clinician group or clinician level, using appropriate attribution. For example, measures of medication adherence can be calculated at the population, plan, clinician group, and clinician levels, using aligned specifications/definitions.
- Developing measures that span settings—this might require adaptation or "versioning" of the same measure (i.e., the same numerator but with a clinician-specific cohort, expanding encounter code sets where appropriate, such as home care).
- Using measures that may not be specific to a care setting, such as PROMs and measures of change in functional status over time.

Approach – CMS will gather stakeholder input related to measures that are applicable across settings of care and types of clinicians (e.g., furthering the evolution of PROMs and consideration of system-level measures to assess care for persons with multiple chronic conditions). MACRA authorizes the Secretary to use certain measures from non-physician health care settings (e.g., hospitals, nursing homes) for purposes of the quality and resource use performance categories.[lxii]

Clinical Practice Improvement Activities

The MACRA requirement –

> "In developing the draft plan under this paragraph, the Secretary shall consider . . . clinical practice improvement activities submitted under [section 1848(q)(2)(C)(iv) of the Act] for identifying possible areas for future measure development and identifying existing gaps with respect to such measures."[lxiii]

Background – The clinical practice improvement activities performance category of MIPS is required to include at least the following subcategories (to which the Secretary may add)[lxiv]:

1. Expanded practice access
2. Population management
3. Care coordination
4. Beneficiary engagement
5. Patient safety and practice assessment
6. Participation in an APM (as defined in section 1833(z)(3)(C) of the Act)

[lxi] Section 1848(s)(1)(C)(ii)
[lxii] Section 1848(q)(2)(C)(ii)
[lxiii] Section 1848(s)(1)(C)(iii)
[lxiv] Section 1848(q)(2)(B)(iii)

These subcategories of clinical practice improvement activities have some overlap with the quality measure domains defined in section 1848(s)(1)(B) of the Act. As professionals identify areas of their practice for improvement, track their results, and engage in continual practice improvement, they may identify areas of true performance gaps that can serve as the basis for new measures and new clinical practice improvement subcategories. The practices of the professionals may serve as sites for new measure development and testing. This provides the opportunity to both improve care at the practice level and inform the broader quality ecosystem through innovative approaches to measurement that may be developed and more widely adopted. Additionally, new and existing measures can suggest areas of improvement to act on to meet CPIA requirements.

Approach – CMS will review clinical practice improvement activity submissions to evaluate whether the activity submitted can be further developed into quality measures within the defined clinical practice improvement activity subcategories. For the purposes of MIPS, specific activities will be established through rulemaking. As an example for illustrative purposes only, clinicians who use patient-reported tools (e.g., *PHQ-9* for depression) for improvement purposes could submit data to CMS from the use of these tools, including administrative survey and experience elements as well as associated patient outcomes (e.g., hospitalizations and emergency visits). This could strengthen the validity of patient-reported outcome measures and lead to the development of potential companion outcome and efficiency measures.

In considering additional options for this performance category, CMS is evaluating comments and recommendations from ABIM and other specialty societies that stressed the importance of leveraging the Choosing Wisely recommendations as a demonstrated method to stimulate and support conversations between clinicians and patients about appropriate care. CMS also is evaluating whether participation in evolving initiatives, such as the National Testing Collaborative, could be applied toward the CPIA performance category score.

Consideration for Electronic Specifications

The MACRA requirement –
> "In selecting measures for development under [section 1848(s) of the Act], the Secretary shall consider . . . whether such measures would be electronically specified."[lxv]

Background – The continued evolution, use, and expansion of electronic clinical quality measurement in CMS quality reporting and performance initiatives are important factors in the transition from volume-based reimbursement to value-based reimbursement. Measures developed from electronic data sources draw from a rich set of clinical data contained within EHR systems and other clinical sources, such as clinical registries.

[lxv] Section 1848(s)(2)(B)(ii)(I)

Compared with traditional data sources, such as administrative claims and hard-copy medical records, electronic data sources may provide improvements such as:

- Incorporation and use of a more robust set of electronic clinical data elements.
- Standardized approach and structure for creating measure specification logic.
- Standardized approach and structure for reporting patient outcomes.
- Increased ability to support more frequent data submission.
- Increased ability to provide actionable, near real-time feedback to ensure reported clinical quality measure data can be used to highlight workflow issues, identify gaps in care, and support root-cause analysis.

Figure 4: Stakeholder Engagement
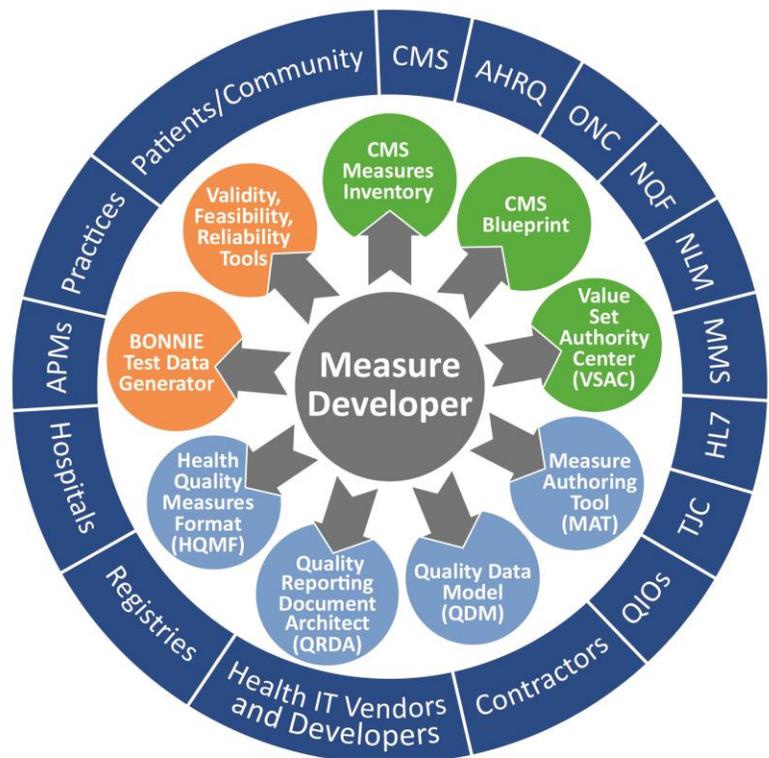
The broader use of electronic data derived from EHRs and clinical registries could simplify the process of capturing, comparing, and evaluating performance results at the individual and population health levels. However, the development and implementation of electronic measures is a complex process that requires close coordination, communication, and collaboration across multiple internal and external stakeholders to be successful, as shown in Figure 4. A phased approach to allow advances in electronic measurement while standards are evolving is essential to successful implementation.

In selecting measures for development for MIPS and advanced APMs, CMS must consider whether proposed measures appear viable for electronic specification. Specifications for electronic measures should be derived from a feasible set of data elements that can be reasonably captured within existing clinical workflows, unless a compelling need is identified for the addition of a new data element. Standard data elements should include and align with, where feasible, ONC Health IT Certification Program requirements for key demographic information required to identify disparities (e.g., race, ethnicity, language). The stakeholder community should aid in test implementations and evaluation of the data elements, workflow, and measure specification. In turn, measure developers must use these data to evaluate industry readiness to implement proposed electronic measures.

To support the identification and use of standard data elements, ONC publicly posts a Data Element Catalog (DEC) as part of the annual update process to provide implementers with the universe of elements included in the electronic specifications. The National Library of Medicine

(NLM), CMS, ONC, and the private sector jointly maintain the DEC, which consists of the measure codes and value sets with their appropriate Quality Data Model data types and attributes. As industry standards such Clinical Quality Language (CQL) continue to evolve, CMS will work closely with ONC to update the DEC and EHR certification requirements to identify and support a common core set of feasible data elements to serve as the framework for future electronic specifications.

A full evaluation of industry readiness cannot be completed until more detailed measure-testing cycles are conducted. CMS intends to leverage a data-driven approach to integrate earlier and broader access to clinical data and metadata originating from patient registries, clinical data repositories, and common data models. CMS can thereby provide measure developers with the standardized data elements necessary to support successful implementation of electronic measures without adding the long delays and costs associated with site recruitment, data acquisition, and field testing by individual measure developers. The clinical community can then provide feedback on these data elements.

This approach will be used to inform measure specifications and criteria (e.g., data element distributions and population, inclusion/exclusion parameters and prevalence, measure logic approaches, value set usability). CMS will leverage stakeholder input and perspectives from evolving initiatives such as:

1. *eCQM National Test Bed and National Testing Collaborative* – An HHS initiative sponsored jointly by CMS and the ONC, the eCQM National Testing Collaborative (NTC) was conceptualized at the February 2013 Lean Kaizen event based on stakeholder analysis of current testing processes for electronic measures. The goal of the collaborative—initially called the "National Test Bed"—is to expand and improve measure development and testing by incorporating earlier and more frequent engagement across stakeholders through all phases of measure development. The conceptual framework has been well received by stakeholders. CMS is continuing to recruit stakeholders from diverse settings and conduct onboarding sessions to determine the types of testing that a prospective participant could support and what point in the development life cycle would be best suited for that support.

   A key future-state goal of the NTC is to serve as an innovation hub to the measure development community through pilot and implementation testing for electronic measures. CMS intends to perform rigorous implementation testing to ensure that eCQMs will be defect-free prior to including them in CMS quality programs. As part of that process, CMS is evaluating how best to leverage the NTC in testing the expected transition CQL standards for electronic measures. The NTC also intends to serve in a matchmaking capacity to identify, vet, and pair prospective test sites with measure developers to promote and support early and frequent engagement in the development process. Other initiatives include the refinement of marketing materials and templates to support broader NTC awareness and participation and the creation of overarching agreements to streamline data acquisition.[43] CMS will also look for opportunities for the NTC to leverage the ONC Tech Lab to support measure testing and implementation.[44]

2. *Closing the Loop in the Learning Health System – Distributed Networks for Electronic Quality Measure Development and Evaluation* – The AcademyHealth Electronic Data Methods Forum is a collaborative project funded through a cooperative agreement with the Agency for Healthcare Research and Quality to advance the methods and infrastructure for research and quality improvement using electronic health data. The objective of this project is to create a test bed that enables rapid development, testing, reporting, and monitoring within a single national framework, based on the concept of common data models and distributed networks (e.g., The National Patient-Centered Clinical Research Network, known as PCORnet).[45] CMS expects to leverage lessons learned and best practices from this effort to support measure development of new measures and additional pilot projects within the NTC and NQF Incubator.

3. *NQF Incubator* – The NQF Incubator was created in early 2015 to support the next generation of innovative, standardized quality measures through an incubation approach to fill measurement gap areas with trial measures ready for testing and implementation. The incubator incorporates data assets and multi-stakeholder expertise to both accelerate existing measure development efforts and build and test measures for future endorsement consideration to drive outcome-based health care measurement.[46] To further evolve the design and approach of the initiative, NQF facilitated a 2-day design session in February 2016 to gather additional public- and private-sector input and recommendations.

   Based on these recommendations in conjunction with broader MDP public comments and continuing virtual design meetings, CMS and NQF are evaluating the potential for additional data sources and pilot projects to be initiated within the Incubator. While a phased approach and additional logistics and funding mechanisms would be necessary, this may include the integration of QCDR and other viable clinical and administrative data sources, including Part D prescription drug data, as well as additional outreach, knowledge sharing, and representation from stakeholders such as specialty societies, associations, and regional health care improvement collaboratives.

Sustained progress across the above initiatives is critical to the future success of electronic measure development and implementation, especially in measurement gap areas where limited data currently exist.

Approach – CMS intends to prioritize the development of electronic measures in a manner that ensures relevance to patients, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. Specifically, CMS, in concert with ONC and the private sector, is championing electronic measure development in the areas of standards, tools, and processes that are open to all measure developers.

- **Standards**: ONC is tasked with managing and driving the development of industry standards to support the electronic measurement ecosystem. CMS works closely with ONC and standards developing organization communities such as Health Level Seven® International (HL7®) and Integrating the Healthcare Enterprise (IHE) to identify approaches to address deficiencies in current standards. Through this ongoing collaboration across HHS agencies and the private sector, CMS is committed to updating

key standards that drive electronic measure development, reporting, and implementation (e.g., Health Quality Measure Format [HQMF], Quality Reporting Document Architecture [QRDA], and the CMS/ONC-owned Quality Data Model [QDM]). While these standards are the backbone of current electronic measure development, CMS recognizes the need to continually evaluate the usability of the current standards to support long-term sustainability. CMS is leveraging best practices and lessons learned through experiences with the current standards to inform the creation of new standards and related clinical content such as CQL and the Fast Healthcare Interoperability Resources (FHIR). CMS will continue working within and across HHS agencies and multi-stakeholder groups such as HL7, the Health Information Technology Standards Committee (HITSC), the QDM workgroup, and the AcademyHealth Electronic Data Methods Forum to meet this need.

- **Tools**: CMS collaborates jointly with ONC and external stakeholders to further the development and/or integration of tools such as these to facilitate electronic measure development[47]:
    - Measure Authoring Tool (MAT) – Allows measure developers to author computable eCQMs specifications based on the current program versions of eCQM standards.
    - Value Set Authority Center (VSAC) – Allows authoring of value sets based on accepted standards (e.g., RxNorm, SNOMED) through a central repository and interface maintained by the National Library of Medicine.
    - Bonnie – Validates electronic measure logic to ensure that the measure is specified as intended through patient scenario testing.
    - JIRA – Provides a central Web-based application for triaging and responding to stakeholder feedback about annual updates on electronic measure releases.

- **Processes**: To drive improvement in electronic measurement processes, CMS and ONC have championed Lean Kaizen events, where a multi-disciplinary stakeholder group worked collaboratively to review current processes, identify inefficiencies, and design improvements in the measure development cycle (i.e., the "future state"). Multiple process improvements have resulted from these events, including a more streamlined and aligned electronic measure annual update process, formalization of external logic and value set review processes, and the establishment and use of the eCQI Resource Center for electronic measure developers. CMS will continue promoting the broader adoption and use of process improvement in MACRA-funded clinical quality measure development efforts. CMS intends to share resulting process improvements and best practices with the broader measure development community through posting on the eCQI Resource Center website, and where applicable, integration into future releases of the CMS Blueprint. Furthermore, ongoing stakeholder feedback forums can provide an opportunity for measure developers to proactively and directly query measure content owners to improve and validate new approaches to data capture and workflow expression within measure specifications.

In addition, CMS and NQF are working closely with ONC and the National Library of Medicine to address harmonization within clinical code vocabularies. Reliable and interoperable clinical quality measurement relies on electronic clinical data standards and reusable code vocabularies, known as value sets, to ensure measures can be consistently and accurately implemented across disparate systems.

The continuing evolution of these standards, tools, and processes will streamline electronic measure development. As progress continues toward electronic measure development from traditional claims submitted measures, CMS realizes that this transition can present challenges for facility-based clinicians, such as hospitalists, who may not have ready access to EHR data and reporting capabilities across the hospitals where they provide care. For these clinicians, CMS intends to investigate alternative approaches to participation while these types of challenges are rectified.

Through the continued multi-stakeholder collaboration across the public and private sectors in initiatives such as the NTC, the AcademyHealth Electronic Data Methods Forum, and the NQF Incubator, and the continued evolution of standards, tools, and processes as noted above, CMS will leverage synergies across these efforts and consider pilot projects that can evolve key MACRA quality domains in alignment with the NQS and CMS Quality Strategy. Public comment and suggestions on the draft MDP identified potential pilots in areas including, but not limited to:
- Approaches to future participation for clinicians not currently eligible for MIPS (e.g., concepts for physical therapists, such as functional status assessments and patient-reported outcomes).
- Behavioral health concepts that promote shared decision-making (e.g., recovery-oriented care).
- Big Data approaches that combine administrative, clinical, and patient-provided data (e.g., oncology measures that incorporate claims, registry, and data derived from social media).
- Evolution and broader use of patient-reported outcomes (e.g., joint replacement).
- Improved participation for non–patient facing clinicians (e.g., concepts regarding accuracy of diagnostic services for radiologists and pathologists).
- Clinician-level attribution of hospital-level measures for specialists (e.g., pathology).
- Team-based care concepts (e.g., concepts that span the surgical care continuum).

CMS intends that all electronic measures—whether new or retooled—go through the testing processes envisioned by the NTC and/or NQF Incubator as part of NQF requirements for endorsement consideration.

Measure Development Plan Timeline

The MACRA requirements –

> ''STAKEHOLDER INPUT.—The Secretary shall accept through March 1, 2016, comments on the draft plan posted under paragraph (1)(A) from the public, including health care providers, payers, consumers, and other stakeholders.''[lxvi]

> ''FINAL MEASURE DEVELOPMENT PLAN.—Not later than May 1, 2016, taking into account the comments received under this subparagraph, the Secretary shall finalize the plan and post on the Internet website of the Centers for Medicare & Medicaid Services an operational plan for the development of quality measures for use under the applicable provisions. Such plan shall be updated as appropriate.''[lxvii]

> "Before including a new measure in the final list of measures published under clause (i) for a year, the Secretary shall submit for publication in applicable specialty-appropriate, peer-reviewed journals such measure and the method for developing and selecting such measure, including clinical and other data supporting such measure."[lxviii]

Background – A timeline for quality measure development activities is a key component of this MDP. Key milestones and processes mandated in MACRA, in conjunction with the pre-rulemaking and federal rulemaking process for clinician measurement programs, anchor the time frame available for measure development. The MAP pre-rulemaking activities are not required under MIPS,[lxix] but the MAP process has proven to be valuable to obtain multi-stakeholder perspective and early engagement.

The time frame for the measure development process depends upon many factors (e.g., type of measure, availability of data, data source, alignment with consensus-based review timelines). CMS is applying Lean principles to the measure development process to allow for more rapid-cycle development and shorter time frames to complete measure testing. CMS prefers to use measures that have been subject to review and endorsement by a consensus-based entity; however, MACRA allows evidence-based measures that are not endorsed to be included,[lxx] which would allow CMS to implement measures while seeking endorsement.

MACRA introduces a new requirement for measures to be included in MIPS. Specifically, the new measure and the method for developing and selecting the measure must be submitted for publication in an applicable specialty-appropriate, peer-reviewed journal.[lxxi] The time frame to prepare a manuscript and adhere to the requirements of a peer-reviewed journal will need to be carefully considered to meet the timeline and requirements of MACRA.

[lxvi] Section 1848(s)(1)(E)
[lxvii] Section 1848(s)(1)(F)
[lxviii] Section 1848(q)(2)(D)(iv)
[lxix] Section 1848(q)(2)(D)(ix)
[lxx] Section 1848(q)(2)(D)(v)
[lxxi] Section 1848(q)(2)(D)(iv)

Approach – The timeline in Figure 5 incorporates key milestones and processes mandated in MACRA (shown in green), in conjunction with the key milestones for the pre-rulemaking (shown in orange) and the expected federal rulemaking cycle for MIPS (shown in blue).

CMS will submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals before including such measures in the final annual list of quality measures. CMS proposes to use the Call for Measures process as an opportunity to gather the information necessary for journal submissions from measure developers, owners, and stewards.

MAP processes, while not required for MIPS, allow CMS to engage stakeholders and obtain their perspectives in the selection of measures to be implemented and suggestions for measures that need to be developed or refined. MACRA specifies that the notice-and-comment rulemaking process will be used to publish the list of measures for MIPS. The list will be published in the *Federal Register* no later than November 1 of the year prior to the performance period.[lxxii] The comment period on the proposed rule will allow opportunities for stakeholder input related to the selection of measures and suggestions for measure development. The first MIPS payment adjustment will be implemented on January 1, 2019, based on a prior performance period.[lxxiii]

Measure Development Plan Annual Updates

The MACRA requirements –
>   "(3) ANNUAL REPORT BY THE SECRETARY.—

>   "(A) IN GENERAL.—Not later than May 1, 2017, and annually thereafter, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a report on the progress made in developing quality measures for application under the applicable provisions."[lxxiv]

>   "(B) REQUIREMENTS.—"Each report submitted pursuant to [section 1848(s)(3)(A) of the Act] shall include . . .

>>   "[a] description of any updates to the plan under [section 1848(s)(1) of the Act] (including newly identified gaps and the status of previously identified gaps) and the inventory of measures applicable under the applicable provisions"[lxxv] and

>>   "[o]ther information the Secretary determines to be appropriate."[lxxvi]

Approach – A progress report summarizing updates to the MDP will be posted to the CMS.gov website annually or otherwise as appropriate. Each progress report will include a summary describing MACRA-funded measure development activities completed during the prior year, as well as measure development efforts that are underway or planned for the near future, including

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[lxxii] Section 1848(q)(2)(D)(i)(I)
[lxxiii] Section 1848(q)(1)(B)
[lxxiv] Section 1848(s)(3)(A)
[lxxv] Section 1848(s)(3)(B)(iv)
[lxxvi] Section 1848(s)(3)(B)(v)

any newly identified measure gap areas,[lxxvii] and any challenges encountered that might result in a delay in completing measures in accordance with the timeline. Detailed tables of measures developed in the preceding year and measures that are under development will accompany the summary information and include specific details about each measure, as required by MACRA. CMS intends to be as transparent as possible in providing this information, but there may be times when information on a given measure development procurement is not available at the time of the posting of the annual progress report. CMS is also evaluating the potential to post the annual progress report in advance of the legislatively mandated date of May 1 each year to provide additional time between the posting of the report and the subsequent Call for Measures process.

Measures Developed the Preceding Year

The MACRA requirement –

"(ii) With respect to the measures developed during the previous year—

"(I) a description of the total number of quality measures developed and the types of such measures, such as an outcome or patient experience measure;

"(II) the name of each measure developed;

"(III) the name of the developer and steward of each measure;

"(IV) with respect to each type of measure, an estimate of the total amount expended under this title to develop all measures of such type; and

"(V) whether the measure would be electronically specified."[lxxviii]

Approach – The annual progress report will include summary and detailed information about the measures developed with MACRA funding during the preceding year and ready for implementation. The summary will include the total number of measures and the number of measures by type, including process measures, PROMs, other outcome measures, and patient experience measures. The total amount of MACRA funding expended will be provided for each type of measure. The summary for each measure type will include the number of electronically specified measures developed.

Detailed information about the measures that have completed development will include:

- Measure name: The title of the measure, which provides the measure focus and target population.
- Measure developer: Individual or organization that designs and builds measures.
- Measure steward: An individual or organization that owns a measure and is responsible for maintaining the measure. Measure stewards are often the same as measure developers. Measure stewards are also an ongoing point of contact for people interested in a given measure.
- Type of measure
  - Process: Measures that assess steps which should be followed to provide good care.

[lxxvii] Section 1848(s)(3)(B)(iv)
[lxxviii] Section 1848(s)(3)(B)(ii)

- ▪ Outcome (other than PROM): Measures that assess the results of health care which patients experience. They include endpoints such as well-being, ability to perform daily activities, and death.
  - ▪ Patient-reported outcome measure: An instrument, scale, or single-item measure that gathers information directly from patients about how they are feeling, their symptoms, and any effects of prescribed treatment.
  - ▪ Patient experience: Measures that use direct feedback from patients and their caregivers, usually collected through surveys, about the experience of receiving care.
  - ▪ Appropriate use: Measures that evaluate both overuse and underuse of health care services.
- • Quality domains: Include clinical care, safety, care coordination, patient and caregiver experience, population health and prevention, and efficiency and cost reduction.
- • Electronically specified: Development of specifications for eCQMs, performance measures for use in an EHR or other electronic system.
- • Data source: For eCQMs, the source(s) for data elements (e.g., a Health Information Exchange, EHR, QCDR, other registry or system). For non-eCQMs, the primary source document(s) used for data collection (e.g., billing or administrative data, encounter form, enrollment forms, medical record).
- • Endorsement status: Whether the measure has been submitted to the consensus-based entity and, if so, the status of the measure in the endorsement process (e.g., endorsed, under review, failed endorsement).

Measures Under Development

The MACRA requirement –

 "(iii) With respect to measures in development at the time of the report—
   "(I) the information described in clause (ii), if available; and
   "(II) a timeline for completion of the development of such measures."[lxxix]

Approach – The annual progress report will include summary and detailed information about the measures developed with MACRA funding that continue to be in the development stage and are not yet ready to be implemented.[lxxx] The summary will include the total number of measures; the count of measures by type, including process measures, PROMs, other outcome measures, and patient experience measures; and the number of measures for each type that will be electronically specified. The summary will describe the number of measures estimated to be completed within 1, 2, and 3 years for each measure type.

Detailed information about the measures that are in development will include the same information as included for the measures that are fully developed, but will also include the estimated date that each measure will be ready for use.

[lxxix] Section 1848(s)(3)(B)(iii)
[lxxx] Section 1848(s)(3)(B)(iii)

**Figure 5: Timeline for Pre-Rulemaking and Rulemaking Activities and Annual Progress Reports**

Legend: ● = MDP Progress Reports and Key Dates   ● = Call for Measures and MAP   ● = NPRM, MIPS Measures, & Final Rulemaking
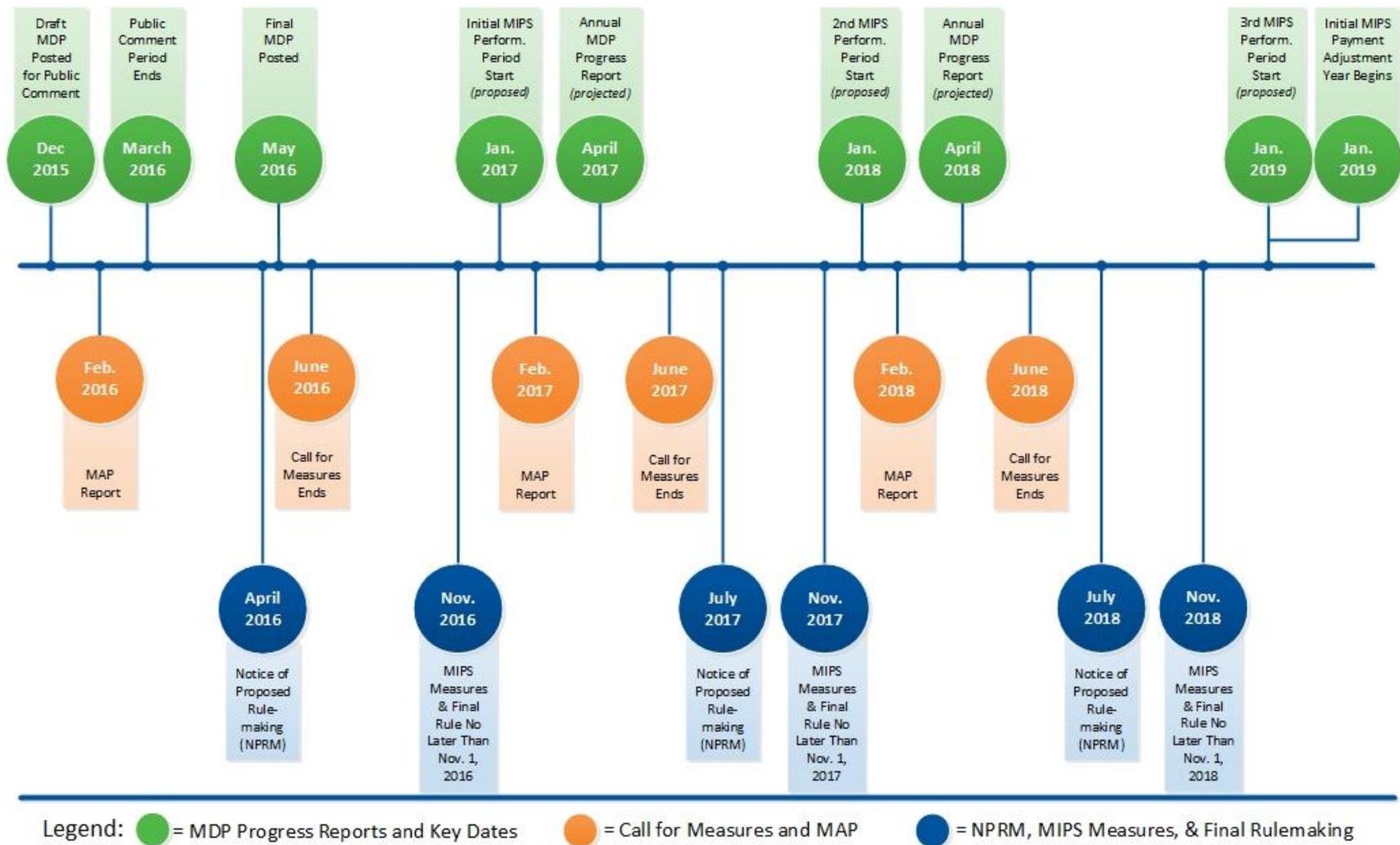
IV. Key Considerations in Quality Measure Development and Potential Strategic Approaches

This section describes key considerations to implementing the MDP, specifically related to measure development, and identifies potential strategic actions to address these challenges.

Partnering With Patients in the Measure Development Process

Background – The development of person-centric measures depends on having the voice of the patient, family, and/or caregiver incorporated throughout the measure development process. Partnering with patients and caregivers means seeking their unique perspectives and expertise and providing support so that they can meaningfully participate. Involving diverse patient and caregiver groups (e.g., children, elderly, home-based, dually eligible) is critically important to ensuring measures are meaningful to all persons.

In 2012, CMS began to require measure developers to include one or more patients or caregivers in the measure development process.[48] Challenges with patient and caregiver engagement include recruitment; need of support and orientation to participate fully; and feelings of intimidation in the presence of subject matter experts engaged in highly technical discussions.

Strategic Approach – CMS evaluates best practices related to patient/caregiver involvement in the measure development process and disseminates this information through a variety of channels, such as measure developer forums and updates to the MMS Blueprint. Recent best practices identified for partnering with patients and caregivers include:

- Adopting principles from the Patient Centered Outcomes Research Institute (PCORI) person-family engagement framework.
- Conducting outreach through patient organizations, other entities that focus on engaging patients (e.g., PatientsLikeMe, Patient-Centered Outcomes Research Institute), and condition-specific organizations (e.g., Arthritis Foundation, Cancer Support Center).
- Screening candidates for background relevant to the measure development project.
- Including patients/caregivers from diverse backgrounds in the measure development process.
- Preparing patients/caregivers by orienting them to the measure development process and their roles.
- Establishing a patient/caregiver mentor on the measure development team.
- Educating meeting facilitators/moderators on how to engage patients and caregivers in discussions.
- Engaging patients and caregivers early in the measure development process to identify concepts that are meaningful to them.
- Prioritizing measure concepts through focus groups or key informant interviews.
- Continuing to partner with patients and caregivers throughout the measure development process, including broader representation in TEPs and patient focus groups.

Partnering With Frontline Clinicians and Professional Societies

Background – CMS is committed to partnering with frontline clinicians and professional societies to identify, select, and develop quality measures that are meaningful to both patients and clinicians. Thus far CMS has made strides in this effort by including professional society members in TEPs and involving expert clinicians in measure testing.

Strategic Approach – CMS will forge new partnerships and strive for transparency to achieve the goals and objectives of MACRA. Specifically, to leverage the invaluable expertise of clinicians and their professional associations, CMS anticipates implementing the following approaches:

- Collaborating with NQF to ensure that clinicians and specialties most affected by proposed measures have sufficient representation in the MAP to guide the selection of the most appropriate, applicable, and meaningful measures.
- Encouraging broader specialty representation in the Core Quality Measures Collaborative and greater transparency in the selection of core measure sets.
- Creating a dedicated Web page to improve clinician and professional society awareness of opportunities to participate in measure identification, selection, and development.
- Exploring ways of pairing professional societies with experts in measure development to share knowledge about their respective processes.
- Providing technical assistance to professional societies to explain the requirements of the MMS Blueprint.
- Encouraging measure developers to engage frontline clinicians in TEP workgroups and measure testing as a source of feedback on feasibility, relevance, and utility of a measure for quality improvement.
- Hosting periodic open door forums or listening sessions related to progressing the development and selection of measures.

Alignment of Measures

Background – Alignment of measures means using the same measure concept across programs (hospital, nursing homes, etc.), across payers (Medicare, Medicaid, VA, DoD, OPM, private insurance), and across payment systems (MA plans, fee-for-service, ACOs). In a 2016 report on clinician measures, the MAP emphasized that alignment is "one of the most important cross cutting priorities."[49]

One challenge associated with alignment of measures across programs is that each program has unique needs. Different data sources and levels of accountability necessitate corresponding measure specifications. However, aligning the measure concepts would align the quality goals; and enable comparison and collaboration across payers, programs, and payment systems; and facilitate consistent implementation.

Strategic Approach – CMS will evaluate conceptual alignment of federal programs during the 2018 Impact Assessment of CMS Quality and Efficiency Measures, a triennial assessment mandated by Congress.[50] Recommendations for alignment between federal partners will be considered by the Measure Policy Council. CMS will also support an NQF evaluation of variation in the detailed measure specifications to provide recommendations. In addition, the MAP will promote alignment through the development of families of measures related to the

NQS priority areas. CMS will continue to work with private payers and other stakeholders in the Core Quality Measures Collaborative to develop consensus on core sets of measures that all payers could use.

Reducing Clinician Burden of Data Collection for Measure Reporting

Background – The rich clinical information contained within the medical record contributes to the development of clinically meaningful measures; however, extracting this information retrospectively outside of the clinical workflow expends valuable time and resources of clinicians and care teams.

Strategic Approach – CMS strives to minimize clinician burden by collecting data that are part of the clinical workflow, while still pursuing measures that are meaningful to consumers and patients. Collecting data directly from patients or caregivers can supplement clinician-generated data for a given measure. CMS also prioritizes the development of measures based on data from EHRs, which can decrease the data collection burden while maintaining measure validity. CMS collaborates with health IT developers and frontline clinicians to maximize the use of clinical workflows to capture information required for quality measurement. To address the burdens of reporting measures, obtaining feedback reports, and other aspects of program design, CMS will obtain the input and perspective of multiple stakeholders on the initial design for MIPS.

CMS will continue to evaluate measures and retire measures that are topped out or weakly correlate with health outcomes, measure basic standards of care, are no longer clinically relevant because of advances in medical treatment, or reinforce incentives to provide low-value care.

Shortening the Time Frame for Measure Development

Background – The length of the measure development process from concept through implementation varies widely as measure developers conduct research, define specifications, test measures, and complete the consensus endorsement process. Under MACRA, new measures for MIPS are not required to be submitted for consensus endorsement; however, they must be evidence-based and submitted for publication in a peer-reviewed journal prior to use in MIPS.[lxxxi] CMS will continue to explore options for this new requirement, which will have an impact on the time frame of measure implementation that has yet to be determined. An extensive period for measure development and implementation would impact the availability of new measures to address measurement gaps (e.g., measures for certain specialties, outcome measures) for MIPS.

Strategic Approach – CMS has already reduced the measure development time frame by incorporating Lean principles into the measure development workflow. For example, measure developers now move measures individually through the development and testing phases (i.e., single-piece flow) rather than waiting for an entire batch of measures to complete one phase. CMS also requires measure developers to have a multi-level, external review process to improve the accuracy, consistency, and efficiency of the HQMF measure logic and the associated value sets. Improved functionality and integration of the MAT and the VSAC tools also have reduced

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[lxxxi] Section 1848(q)(2)(D)(iv), (v)

measure development time. CMS will promote the continued adoption of Lean principles to further reduce waste throughout the measure development process and is exploring the application of industry best practices, such as agile development, to the measure development process.

To further reduce the timeline for measure development, CMS will facilitate cross-developer transparency and knowledge sharing through established forums and expanded use of the CMS measure developer library. The Web-based library stores documents and work products from measure development projects across CMS. CMS also is upgrading the publicly posted CMS Measures Inventory—a compilation of measures used by CMS in various quality, reporting, and payment programs—into a Web-based CMS Measure Inventory Tool that will include measures under development.

Knowledge sharing between measure developers assists in the rapid development of measures. For example, sharing measure specifications and computer programming code for similar measures reduces duplication of effort, minimizes overlap, and increases efficiency. As CMS implements these important improvements, MACRA-funded measure developers should be able to complete initial measure development tasks in a more efficient and timely manner, while eliminating delays and rework that occur when multiple stakeholders unknowingly are developing similar measures or concepts.

To minimize the impact of the journal submission requirement to measure development timelines, CMS will build efficiencies and standards into the process and coordinate journal submissions.

Streamlining Data Acquisition for Measure Testing

Background – Individual measure developers currently have to identify and recruit providers to participate in measure testing activities, a costly and time-consuming process. Each developer is responsible for negotiating data use and business associate agreements and contractual logistics with providers to access clinical data to support measure testing. In addition, the number of providers that can participate in measure testing activities is constrained by the limited resources available to each measure developer. Requests from multiple measure developers for participation in measure testing likewise strain the resources of providers.

Strategic Approach – CMS will leverage broader data sources for measure development to support the continued evolution of the NTC and the NQF Incubator. A key objective of the NQF Incubator is to make clinical data available to measure developers to refine evolving concepts, build new measures, and accelerate testing for existing measures for which data are not yet widely available in the field. CMS also intends to increase flexibility in data sharing and reuse by measure developers.

The data-driven approaches envisioned across these initiatives would inform early measure specification development, enhance testing of measure reliability and validity, facilitate risk adjustment of outcome measures, and improve patient attribution algorithms. In turn, costs and time for developers to acquire data would be reduced, while the number of stakeholders participating in measure development and testing would be expanded.

To achieve measurable success in these initiatives, CMS understands the critical importance of interoperability in accelerating connectivity and health information exchange. To that end, CMS and ONC are working with the private sector to improve access to patient data. Recent efforts have yielded commitments from public- and private-sector stakeholders to eliminate practices—deliberate or otherwise—that restrict access to or exchange of data A list of organizations that have pledged to work together against so-called data blocking is available at https://www.healthit.gov/commitment.

Identifying and Developing Meaningful Outcome Measures

Background – Two key considerations for outcome measurement relate to the identification of meaningful outcomes (i.e., assessing gaps in clinical care and performance) and the development of valid risk-adjustment models. Equitably evaluating clinician performance for outcome measures requires careful evaluation of associated patient risk factors (e.g., age, comorbidities), yet limited sample sizes and data availability constrain the development of risk-adjustment models.

Strategic Approach – Defining measures with meaningful outcomes starts with the consideration and integration of the patient/caregiver perspective, which CMS is accomplishing by providing patients and caregivers more prominent roles in measure development. CMS will strive for inclusion of persons with diverse racial and ethnic backgrounds, limited English proficiency, mobility impairment or other disabilities, and lower levels of health literacy, among other challenges that may lead to disparities in health and health care among vulnerable populations.

Integrating individuals' health concerns, preferences, and goals into measure design is an approach that holds promise for producing meaningful, person-centered outcome measures. With such variables incorporated into EHRs, quality measurement could be part of care delivery rather than a parallel system.

Patient/caregiver input will be balanced with the frontline clinician perspective and with evidence-based research. Currently CMS is participating in an NQF pilot project to evaluate incorporation of sociodemographic factors into risk-adjustment models. ASPE also is conducting research on this issue, as directed by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. CMS has been collaborating closely with ASPE on the implementation and analyses of this research, on which ASPE will issue a report to Congress by October 2016.

CMS is promoting collaboration among measure developers in the development of risk-adjustment methodologies and exploring the use of EHR data as a source of risk factors. The development and expansion of the NTC should increase the availability of data to identify and test data elements for incorporation into risk-adjustment models. CMS anticipates a phased approach to obtaining more robust data for risk adjustment.

Developing PROMs and Appropriate Use Measures

Background – MACRA prioritizes the development of patient experience, care coordination, appropriate use, and patient-reported outcome measures.[lxxxii] These types of measures historically have been challenging to develop in an efficient and consistent manner that assures validity of the response without placing excessive burden on the patient. For PROMs, the data may not be collected during the provision of clinical care, and the infrastructure to collect and store these data has not been widely available and standardized.

For appropriate use (e.g., overuse) measures, availability of data has constrained measure development, as evidenced by a recent study evaluating eCQM readiness. In March 2015, the RAND Corporation published a report to evaluate the viability of translating 45 Choosing Wisely concepts into performance measures based on data contained within EHRs.[51] The results indicated that 32 of the 45 recommendations required data elements not usually found in the current EHR systems. These findings appear consistent with results for traditional measures.

Recently, the Choosing Wisely campaign has expanded to include more than 300 recommendations from 70 organizations.[42] Founded as an effort to support dialogue between patient and clinician, the campaign acknowledges that there are persons and circumstances for which deviations from criteria of appropriate use might be justifiable and that variation is to be expected.

Strategic Approach – To initiate the development of PROMs, CMS introduced several "building block" measures as part of the Medicare EHR Incentive Program.[52] For example, process measures capturing pre- and post-surgical functional status assessment for hip and knee replacement surgery and congestive heart failure were developed and included as part of Meaningful Use Stage Two.[53] These process measures provide the foundational framework for capturing PROM data within EHR systems and bridge the gap to future corresponding outcome measures. To facilitate the transition from building-block process measures to corresponding PROMs, CMS will need to develop and test PROMs based in part on the data received from the existing process measures.

CMS will explore capturing PROM information at relevant points of care, using dynamic, algorithmically selected approaches to choose appropriate items. CMS may also explore the development of an interoperable, private data-sharing method that allows for PROMs to be collected, integrated into the EHR, used, and interpreted by every member of the care team, including patients and family caregivers.

Remote monitoring technologies such as telehealth and smartphone applications (apps) might be leveraged to engage patients in collecting PROMs. Patient-focused health data portals such as PatientsLikeMe are another potential method for the collection of patient data. Emerging initiatives such as a joint HHS and U.K. National Health Service cooperative related to PROMs could yield still others.[54] When feasible, CMS will avoid using proprietary tools for PROMs.

[lxxxii] Section 1848(s)(1)(D)

CMS will carefully evaluate the viability of developing appropriate use measures based on the Choosing Wisely recommendations. CMS will consult with the ABIM and other relevant specialty organizations to examine the intent of the concepts and whether local adoption and use of Choosing Wisely precepts by MIPS eligible clinicians would be best suited for another MIPS performance category, such as clinical practice improvement activities. CMS also will promote the development of balancing measures that serve to mitigate unintended consequences, such as underuse of services.

Finally, CMS will encourage the development of appropriate use measures through the NTC, the AcademyHealth Electronic Data Methods Forum, and the NQF Incubator.

Developing Measures That Promote Shared Accountability Across Settings and Providers

Background – Measures in the PQRS, VM, and Medicare EHR Incentive Program for Eligible Professionals assess individual or group practice-level performance rather than holding more than one clinician or other provider type accountable for a person's care. As health care settings evolve toward population-based payments that hold multiple provider types accountable for the health of populations, CMS must adapt and use measures that reflect this shared accountability. Measures of shared accountability should reflect careful attribution of responsibilities among clinicians delivering care for the same patient population. Measures of shared accountability could also reflect shared partnership with patients in achieving their health care goals.

Furthermore, developing measures of shared accountability requires improved provider coordination across care settings and interoperable health information exchange among a variety of health care stakeholders, including clinicians, laboratories, health plans, payers, and patients. While initial progress has been made in these areas, sustained improvement is dependent on broad-based adoption and use of health information exchange to provide the framework for data-driven measure development and attribution.

Strategic Approach – Agencies across HHS are working to increase the adoption and use of health information exchange through longstanding relationships with the National Committee on Vital and Health Statistics (NCVHS) and industry partners such as the Workgroup for Electronic Data Interchange and the Council for Affordable Quality Healthcare. To encourage adoption more broadly across settings, CMS proposes to[55]:

- Enable health information exchange, where possible, in support of state-led delivery and payment reform through federal and state partnerships.
- Evaluate the potential for organizations that facilitate health information exchange to report quality measurements on behalf of providers.
- Encourage interoperability across states' electronic health information infrastructures, including Medicaid and state survey agencies.
- Continue stakeholder collaboration to facilitate the adoption and use of health IT standards and interoperability requirements.

The challenge in developing measures of shared accountability is determining the proximal process or outcome for which each provider can take responsibility. Recognizing that appropriate approaches for attribution need to be explored, CMS is working with NQF and other stakeholders to develop guidance for developing measures of shared accountability.

To promote improved collaboration across providers, CMS intends to incorporate both primary care and specialist accountability across care settings and through phases of a clinical episode of care. For example, the EHR Incentive Program building block measure *PQRS #374: Closing the Referral Loop – Receipt of Specialist Report* evaluates the effectiveness of tracking referrals from the primary care physician to the specialist. CMS is considering expansion of this measure to include specialist reports to primary care physicians.

V. Summary of Priorities and Gaps

CMS has identified initial priorities for each of the domains through input from multi-stakeholder groups (e.g., the MAP), recent publications (e.g., IOM *Vital Signs*), federal reports (e.g., HHS *National Action Plan on Adverse Drug Event Prevention*), stakeholder input from public comment on the draft plan, and a preliminary analysis of the PQRS preferred measure sets by specialty. Through ongoing collaboration with stakeholders and during the rulemaking process, CMS may identify additional priority topics and gaps; therefore this list will be continually refined and updated.

Initial Priorities for Measure Development by Quality Domain

Clinical Care

- Measures incorporating personal preferences and shared decision-making
- Outcome measures
- Cross-cutting measures that may apply to more than one specialty
  - System-level measures to assess care for persons with multiple chronic conditions
  - Team-based care concepts (e.g., concepts that span the surgical care continuum)
- Focused measures for specialties that have clear gaps, such as but not limited to:
  - Orthopedic surgery
  - Palliative care
  - Pathology
  - Radiology
  - Mental health and substance use conditions
  - Oncology

Safety

- Measures of diagnostic accuracy
- Medication safety such as related to the following drug classes:
  - Anticoagulants
  - Diabetes agents
  - Opioids

Care Coordination

- Assessing team-based care (e.g., timely exchange of clinical information)
- Effective use of new technologies such as telehealth

Patient and Caregiver Experience

- PROMs
  - Specialty-specific PROMs, including patient experience surveys
- Additional topics that are important to patients and families/caregivers, such as:
  - Knowledge, skill, and confidence for self-management
  - Whether the clinician acted in accordance with personal preferences
  - Participation of family members in care discussions or electronic communications

Population Health and Prevention
- Developing or adapting outcome measures at a population level, such as a community or other identified population, to assess the effectiveness of the health promotion and preventive services delivered by professionals. IOM *Vital Signs* topics for consideration:
    - Life expectancy
    - Well-being
    - Overweight and obesity
    - Addictive behavior
    - Unintended pregnancy
    - Healthy communities
    - Preventive services
    - Community engagement
- Detection or prevention of chronic disease (e.g., chronic kidney disease)

Affordable Care
- Overuse measures (e.g., overuse of clinical tests/procedures)

VI. Conclusion

The MDP defines a strategic framework for the future development of clinician quality measures to comprehensively address operational requirements of section 102 of MACRA. The MDP leverages existing CMS measurement strategies, policies, and principles and input from diverse stakeholders to support the successful transition to MIPS and APMs. CMS will draw from a strong foundation in the development and use of quality measures for the PQRS, VM, Medicare EHR Incentive Program, and other programs to accelerate the transition to value-based payment for eligible clinicians serving the Medicare population.

Organizations developing measures under CMS contracts or collaborating with CMS on measure development will integrate the foundational pillars of the CMS Quality Strategy, Physician Quality Reporting Programs Strategic Vision, MMS Blueprint, and CMS General and Technical Principles. The MDP will be updated annually, or otherwise as appropriate, to report progress and challenges encountered. Updates will include newly identified measure gaps, activities conducted, and lessons learned from key initiatives (e.g., NQF Disparities Project). As the measure portfolio for MIPS and APMs takes shape, CMS periodically will examine the effectiveness of the plan as a living document that responds to the changing circumstances of the health care delivery system.

CMS is committed to reducing clinician burden by leading key measure alignment efforts across federal and private-payer quality reporting programs. These efforts will stress harmonization of data elements and specifications among measure developers, whose cooperation and sharing are essential to creating aligned measures. CMS anticipates that this alignment will lead to more focused quality improvement efforts, which in turn may improve health outcomes. CMS also intends to leverage the optional pre-rulemaking process and MAP review for MIPS and to participate with other stakeholders in efforts that promote measure alignment. The MDP acknowledges key considerations and identifies opportunities for measure developers to share information to reduce duplication of efforts.

The successful implementation of the MDP depends on a successful partnership with patients, frontline clinicians, and professional organizations and collaboration with other diverse stakeholders to develop measures that are meaningful to patients and clinicians and can be used across payers and health care settings. The new measures will address critical measure gaps; facilitate alignment across federal, state, and private programs; and promote efficient data collection while balancing individual and shared provider accountability. CMS will carefully balance the need for focused specialty measure development with the need for more broad cross-cutting measures. The resulting person-centered portfolio will be a key lever of delivery system reform, furthering the aims of Better Care, Smarter Spending, and Healthier People.

Appendix I – CMS General and Technical Principles

General Principles

- Develop measures that explicitly align with the CMS Quality Strategy and its goals and objectives.
- Align with other payers, including Medicaid, other federal partners, and private payers.
- Address a performance gap where there is known variation in performance, not just a measure gap, and where there is an important opportunity to advance population health.
- Partner with patients/caregivers throughout the measure development process to focus on what is best for patients and to integrate personal goals and preferences into appropriate measures.
- Develop measures in a rapid-cycle fashion in accordance with Lean[56,57] principles.[lxxxiii]
- Collaborate with other developers freely and share best practices and new learning.
- Reorient and align measures with person-centered outcomes that span settings, which may require different versions of the same measure (e.g., different cohorts but same numerator).
- Focus on outcomes (including patient-reported outcomes, such as functional status after knee replacement), safety, patient experience, care coordination, and appropriate use.
- Develop measures meaningful to patients/caregivers, clinicians, and the general public.
- Strive to identify and eliminate disparities in the delivery of care.
- Guard against unintended consequences of measure implementation, including overuse and underuse of care.
- Engage stakeholders early and often in the measure development process.
- Reduce clinician burden in reporting measures.

Technical Principles

- Develop a rigorous business case for an evidence-based measure concept—a critical first step in the development process.
- Prioritize electronic data sources (e.g., EHRs, registries) over data from claims and chart-abstraction when feasible, while maintaining measure reliability and validity, and allowing enough lead time for industry readiness and implementation.
- Maintain a focus on iterative testing using both synthetic and real data.
- Consider approaches to aggregate multiple data sources to achieve the most accurate assessment of quality until universal interoperability can be achieved.
- Define outcomes, risk factors, cohorts, and inclusion/exclusion criteria based on clinical and empirical evidence.

[lxxxiii] Lean is a concept first developed by Toyota Manufacturing Company in the early 20th century. The focus of Lean is to provide value to the customer while reducing all forms of waste. Lean principles evolved over time as Lean was adopted by other industries. Womack and Jones identified five Lean principles: Provide the value customers actually desire; Identify the value stream and eliminate waste; Line up the remaining steps to create continuous flow; Pull production based on customers consumption; Start over in a pursuit of perfection: "the happy situation of perfect value provided with zero waste."

- Judiciously select exclusions to ensure that measures capture as broad a patient population as is possible and appropriate (e.g., not excluding patients with behavioral health conditions).
- Develop risk-adjustment models to distinguish performance between clinicians rather than predict patient outcomes.
- Include measure stratification and risk -adjustment approaches to patient demographic characteristics that promote equitable quality comparisons without masking disparities or resulting in unintended consequences for vulnerable populations.
- Harmonize measure methodologies, data elements, and specifications when applicable and feasible.
- Strive to develop each measure with sufficient statistical power to detect and report statistically significant differences in clinician performance, based on available data sources.
- Consider strategies to allow clinicians with smaller practices and low-volume facilities to reliably report a measure.
- Strive to develop measures that can progress multi-payer applicability through the use of all-payer databases where available.

Appendix II – 2016 PQRS Preferred Specialty Measure Sets

2016 PQRS Preferred Specialty Measure Set	PQRS Preferred Measures	PQRS Preferred Measures[1,2] Across NQS Domain Areas						
		Outcome	Effective Clinical Care	Patient Safety	Communication and Care Coordination	Person and Caregiver-Centered Experience and Outcomes	Efficiency and Cost Reduction	Community/ Population Health
Cardiology	17	(n=5) PQRS #236 PQRS #242 PQRS #348 PQRS #392 PQRS #393	(n=10) PQRS #5 PQRS #6 PQRS #7 PQRS #8 PQRS #204 PQRS #236 PQRS #242 PQRS #326 PQRS #399 PQRS #438	(n=3) PQRS #348 PQRS #392 PQRS #393			(n=3) PQRS #322 PQRS #323 PQRS #324	(n=1) PQRS #226
Dermatology	6		(n=1) PQRS #337		(n=4) PQRS #137 PQRS #138 PQRS #265 PQRS #397		(n=1) PQRS #224	
Emergency Medicine	9		(n=4) PQRS #54 PQRS #91 PQRS #254 PQRS #255				(n=5) PQRS #66 PQRS #93 PQRS #116 PQRS #415 PQRS #416	
Gastroenterology	11	(n=1) PQRS #343	(n=6) PQRS #113 PQRS #343 PQRS #387 PQRS #400 PQRS #401 PQRS #438		(n=2) PQRS #185 PQRS #320	(n=1) PQRS #390	(n=1) PQRS #439	(n=1) PQRS #226

2016 PQRS Preferred Specialty Measure Set	PQRS Preferred Measures[1,2] Across NQS Domain Areas							
	PQRS Preferred Measures	Outcome	Effective Clinical Care	Patient Safety	Communication and Care Coordination	Person and Caregiver-Centered Experience and Outcomes	Efficiency and Cost Reduction	Community/ Population Health
General Practice/Family Practice	38	**(n=8)** PQRS #1 PQRS #236 PQRS #242 PQRS #338 PQRS #342 PQRS #343 PQRS #383 PQRS #398	**(n=18)** PQRS #1 PQRS #5 PQRS #41 PQRS #112 PQRS #113 PQRS #117 PQRS #204 PQRS #236 PQRS #242 PQRS #326 PQRS #337 PQRS #338 PQRS #343 PQRS #387 PQRS #398 PQRS #400 PQRS #418 PQRS #438	**(n=3)** PQRS #154 PQRS #181 PQRS #383	**(n=2)** PQRS #155 PQRS #391	**(n=4)** PQRS #50 PQRS #109 PQRS #342 PQRS #390	**(n=8)** PQRS #65 PQRS #66 PQRS #93 PQRS #116 PQRS #331 PQRS #332 PQRS #333 PQRS #334	**(n=3)** PQRS #317 PQRS #394 PQRS #402
General Surgery	12	**(n=8)** PQRS #258 PQRS #259 PQRS #260 PQRS #347 PQRS #354 PQRS #355 PQRS #356 PQRS #357	**(n=2)** PQRS #356 PQRS #357	**(n=9)** PQRS #21 PQRS #22 PQRS #23 PQRS #258 PQRS #259 PQRS #260 PQRS #347 PQRS #354 PQRS #355		**(n=1)** PQRS #358		

2016 PQRS Preferred Specialty Measure Set	PQRS Preferred Measures	PQRS Preferred Measures[1,2] Across NQS Domain Areas						
		Outcome	Effective Clinical Care	Patient Safety	Communication and Care Coordination	Person and Caregiver-Centered Experience and Outcomes	Efficiency and Cost Reduction	Community/ Population Health
Hospitalist	8	(n=1) PQRS #187	(n=5) PQRS #5 PQRS #8 PQRS #32 PQRS #187 PQRS #407	(n=2) PQRS #76 PQRS #130	(n=1) PQRS #47			
Internal Medicine	31	(n=3) PQRS #1 PQRS #236 PQRS #242	(n=17) PQRS #1 PQRS #5 PQRS #9 PQRS #41 PQRS #112 PQRS #113 PQRS #117 PQRS #163 PQRS #204 PQRS #236 PQRS #242 PQRS #326 PQRS #387 PQRS #400 PQRS #401 PQRS #418 PQRS #438	(n=2) PQRS #154 PQRS #181	(n=1) PQRS #155	(n=3) PQRS #50 PQRS #109 PQRS #390	(n=5) PQRS #116 PQRS #331 PQRS #332 PQRS #333 PQRS #334	(n=3) PQRS #134 PQRS #226 PQRS #317
Mental Health	7	(n=1) PQRS #383		(n=2) PQRS #181 PQRS #383	(n=2) PQRS #325 PQRS #391			(n=3) PQRS #134 PQRS #226 PQRS #402

2016 PQRS Preferred Specialty Measure Set	PQRS Preferred Measures	PQRS Preferred Measures[1,2] Across NQS Domain Areas						
		Outcome	Effective Clinical Care	Patient Safety	Communication and Care Coordination	Person and Caregiver-Centered Experience and Outcomes	Efficiency and Cost Reduction	Community/ Population Health
Multiple Chronic Conditions	16	(n=1) PQRS #236	(n=2) PQRS #48 PQRS #236	(n=4) PQRS #130 PQRS #154 PQRS #181 PQRS #238	(n=5) PQRS #46 PQRS #47 PQRS #131 PQRS #155 PQRS #374			(n=5) PQRS #110 PQRS #111 PQRS #128 PQRS #134 PQRS #226
Obstetrics/ Gynecology	17	(n=4) PQRS #236 PQRS #432 PQRS #433 PQRS #434	(n=8) PQRS #39 PQRS #41 PQRS #48 PQRS #112 PQRS #204 PQRS #236 PQRS #309 PQRS #418	(n=4) PQRS #422 PQRS #432 PQRS #433 PQRS #434	(n=1) PQRS #265	(n=1) PQRS #50		(n=3) PQRS #226 PQRS #310 PQRS #317
Oncology/ Hematology	8		(n=6) PQRS #67 PQRS #68 PQRS #69 PQRS #70 PQRS #71 PQRS #72			(n=2) PQRS #143 PQRS #144		
Ophthalmology	16	(n=9) PQRS #141 PQRS #191 PQRS #192 PQRS #303 PQRS #304 PQRS #384 PQRS #385 PQRS #388 PQRS #389	(n=9) PQRS #12 PQRS #14 PQRS #18 PQRS #117 PQRS #140 PQRS #191 PQRS #384 PQRS #385 PQRS #389	(n=2) PQRS #192 PQRS #388	(n=2) PQRS #19 PQRS #141	(n=2) PQRS #303 PQRS #304		(n=1) PQRS #226

2016 PQRS Preferred Specialty Measure Set	PQRS Preferred Measures[1,2] Across NQS Domain Areas							
	PQRS Preferred Measures	Outcome	Effective Clinical Care	Patient Safety	Communication and Care Coordination	Person and Caregiver-Centered Experience and Outcomes	Efficiency and Cost Reduction	Community/ Population Health
Pathology	8		(n=5) PQRS #99 PQRS #100 PQRS #249 PQRS #250 PQRS #251		(n=3) PQRS #395 PQRS #396 PQRS #397			
Physical Therapy/ Occupational Therapy	19	(n=6) PQRS #218 PQRS #219 PQRS #220 PQRS #221 PQRS #222 PQRS #223	(n=2) PQRS #126 PQRS #127	(n=3) PQRS #130 PQRS #154 PQRS #181	(n=10) PQRS #131 PQRS #155 PQRS #182 PQRS #217 PQRS #218 PQRS #219 PQRS #220 PQRS #221 PQRS #222 PQRS #223			(n=4) PQRS #128 PQRS #134 PQRS #226 PQRS #431
Radiology	22	(n=3) PQRS #259 PQRS #344 PQRS #345	(n=4) PQRS #344 PQRS #345 PQRS #405 PQRS #406	(n=4) PQRS #156 PQRS #259 PQRS #360 PQRS #361	(n=7) PQRS #147 PQRS #225 PQRS #265 PQRS #359 PQRS #362 PQRS #363 PQRS #364	(n=3) PQRS #143 PQRS #144 PQRS #358	(n=4) PQRS #102 PQRS #322 PQRS #323 PQRS #324	
Urology	8		(n=3) PQRS #48 PQRS #104 PQRS #119		(n=1) PQRS #265	(n=2) PQRS #50 PQRS #358	(n=1) PQRS #102	(n=1) PQRS #431

[1]Preferred measures are defined as measures most relevant for the eligible professionals within a particular scope of practice or specialty.

[2]The preferred measures listed are suggested measures for specific specialties. They are derived from denominator coding and the clinical concept being measured within the PQRS specification. For additional information, see: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/measurescodes.html

Glossary of Acronyms/Abbreviations

ABIM®	American Board of Internal Medicine®
ABMS®	American Board of Medical Specialties®
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AOA	Administration on Aging
APM	alternative payment model
ARRA	American Recovery and Reinvestment Act of 2009
ASPE	Office of the Assistant Secretary for Planning and Evaluation
CAD	coronary artery disease
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
Collaborative	Core Quality Measures Collaborative
CPIA	clinical practice improvement activity
CQL	Clinical Quality Language
DEC	Data Element Catalog
DoD	Department of Defense
EHR	electronic health record
eCQI	electronic clinical quality improvement
eCQM	electronic clinical quality measure
eMIG	Electronic Measures Issues Group
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
HCPLAN	Health Care Payment Learning and Action Network
HHS	Health and Human Services (U.S. Department of)
HHS Decision Rules	*HHS Decision Rules for Categorizing Measures of Health, Health Care Quality, and Health Care Affordability*
HIMSS	Healthcare Information and Management Systems Society
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009
HITSC	Health Information Technology Standards Committee
HIV	human immunodeficiency syndrome
HL7®	Health Level Seven® International
HQMF	Health Quality Measure Format
HRSA	Health Resources and Services Administration
HSAG	Health Services Advisory Group, Inc.
ICD	implantable cardioverter-defibrillator
IHE	Integrating the Healthcare Enterprise
IHS	Indian Health Service
IMPACT Act	Improving Medicare Post-Acute Care Transformation Act of 2014
INR	International Normalized Ratio

IOM	Institute of Medicine
IT	information technology
MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MAP	Measure Applications Partnership
MAT	Measure Authoring Tool
MDP	Measure Development Plan
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MIPS	Merit-based Incentive Payment System
MMS	Measures Management System
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007
MPC	Measure Policy Council
NCVHS	National Committee on Vital and Health Statistics
NIH-NLM	National Institutes of Health-National Library of Medicine
NPRM	notice of proposed rulemaking
NQF	National Quality Forum
NQS	National Quality Strategy
NTB	National Test Bed
NTC	National Testing Collaborative
ONC	Office of the National Coordinator for Health Information Technology
OPM	Office of Personnel Management
PCMH	Patient-Centered Medical Home
PCORnet[SM]	The National Patient Centered Clinical Research Network[SM]
PCORI	Patient Centered Outcomes Research Institute
PQRS	Physician Quality Reporting System
PROM	patient-reported outcome measure
QCDR	qualified clinical data registry
QDM	Quality Data Model
QRDA	Quality Reporting Document Architecture
RFI	request for information
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
TEP	technical expert panel
TJC	The Joint Commission
U.K.	United Kingdom
VM	Value Modifier
VSAC	Value Set Authority Center

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