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

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

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

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Prepared by: Health Services Advisory Group, Inc.

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I. Executive Summary

Background

A transformation of the U.S. healthcare delivery system gained momentum in 2010 with the passage of the Patient Protection and Affordable Care Act (Affordable Care Act).[1] The law established the Health Insurance Marketplace to extend consumer access to affordable care through private payers and provided strong incentives in publicly financed healthcare programs to connect provider payment to quality of care and efficiency.

Building on the principles and foundation of the Affordable Care Act, the Administration 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. These are measurable goals to move the Medicare program and our healthcare system at large toward paying providers based on quality, rather than quantity, of care.[2]

The passage of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA)[3] supports the ongoing transformation of healthcare delivery by furthering the development of new Medicare payment and delivery models for physicians and other clinicians. Section 102 of MACRA[4,i] requires that the Secretary of Health and Human Services 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 certain Medicare alternative payment models (APMs).

The law provides both a mandate and an opportunity for the Centers for Medicare & Medicaid Services (CMS) to leverage quality measure development as a key driver to further the aims of the CMS Quality Strategy:
- Better Care,
- Smarter Spending, and
- Healthier People.[5]

Measure Development Plan Purpose

The purpose of the CMS Quality Measure Development Plan (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 APMs. CMS welcomes comments on this draft plan from the public, including healthcare providers, payers, consumers, and other stakeholders, through March 1, 2016.[ii] The final MDP, taking into account public comments on this draft plan, will be posted on the CMS.gov website by May 1, 2016, followed by updates annually or as otherwise appropriate.[iii]

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[i] Section 1848(s)(1)(A)
[ii] Section 1848(s)(1)(E)
[iii] Section 1848(s)(1)(F), (3)(A)

The MDP highlights known measurement and performance gaps and recommends approaches to close those gaps through development, use, and refinement of quality measures. CMS draws from extensive experience in these processes and shares with its federal partners a commitment to promoting harmonization and alignment across programs, settings, and payers. We solicit comment on how CMS can further these objectives,

CMS will solicit additional input from stakeholders through the annual Call for Measures[iv] and will begin 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. Updates to the MDP will prioritize the development of additional quality measures in identified gap areas and other priority areas using MACRA funding over the next five years.[v]

Merit-Based Incentive Payment System

Beginning in 2019,[vi] CMS will apply a positive, negative, or neutral payment adjustment to each MIPS EP based on a composite performance score across four performance categories[vii]:
- Quality
- Resource use
- Clinical practice improvement activities
- 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. 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 (EPs), commonly referred to as Meaningful Use.

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 developing new (de novo) measures according to priorities described in Section IV.

To accelerate the alignment of quality measurement and program policies, MACRA sunsets payment adjustments for PQRS, VM, and the EHR Incentive Program and establishes MIPS.

Alternative Payment Models

MACRA establishes incentive payments for EPs participating in certain types of APMs.[ix] MACRA requires quality measures used in APMs to be 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.

[iv] Section 1848(q)(2)(D)(ii)
[v] Section 1848(s)(6)
[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 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
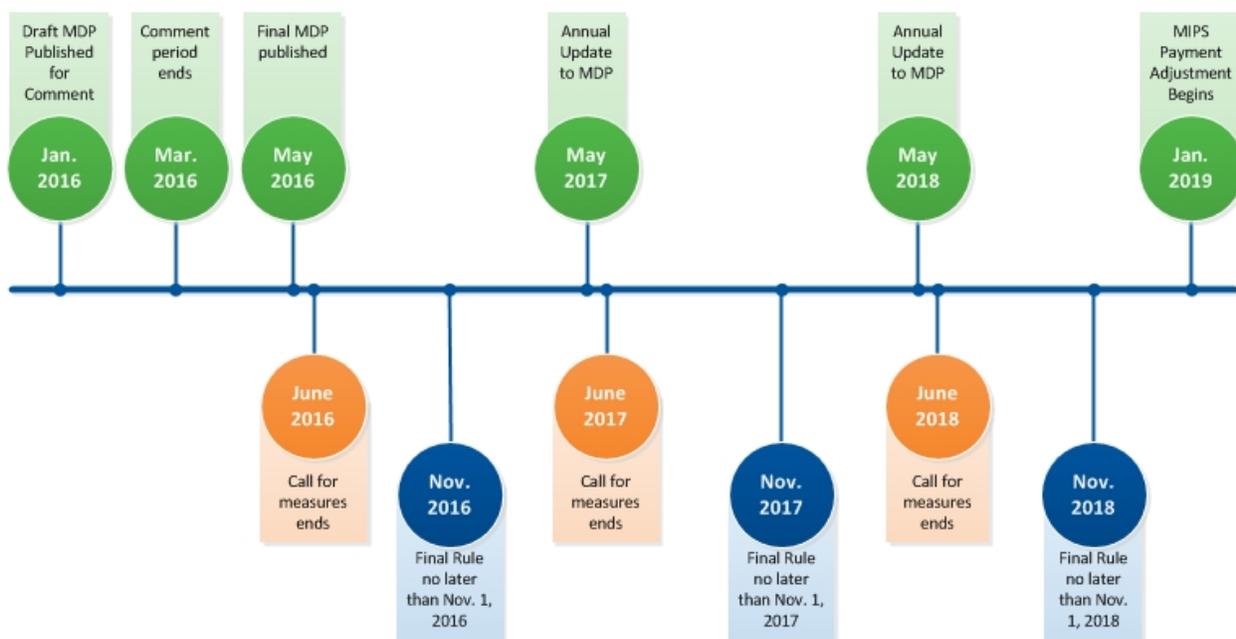
Operational Requirements of MACRA

In Section IV we describe the requirements of MACRA pertaining to this MDP and detail 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 reducing data capture and measure variation.

Strategic Approach – CMS will leverage the Measure Applications Partnership (MAP) and other multi-stakeholder groups to identify creative solutions for use of measures across multiple payers and delivery systems from both the private and public sectors to streamline provider reporting.

[xi] Section 1848(s)(1)(F), (3)(A)
[xii] Section 1848(s)(1)(A)(i)

Coordination and Sharing Across Measure Developers

Overview – Measure developers are required 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 implement new ways to foster communication and knowledge sharing. CMS coordinates measure development efforts across federal agencies through forums such as the Measure Policy Council and eCQM Governance Group calls.

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]

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 exempted from these requirements.

Strategic Approach – CMS requires the development of a rigorous business case to prioritize measures for development. CMS will ensure an evidence-based focus by evaluating new measures throughout the development process, using established criteria. Further, the submissions of new measures for MIPS to peer-reviewed journals will be published on the CMS.gov website.

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

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)[xix] for measures developed under the MDP, which align with the National Quality Strategy and the CMS Quality Strategy.[6] CMS is also taking into consideration the quality domain of efficiency and cost reduction. 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.

Strategic Approach – CMS will collaborate with specialty groups and associations to develop measures that are important to both patients and providers and that represent important performance gaps in the targeted quality domains. When considering measures, CMS will prioritize outcomes, person and caregiver experience, communication and care coordination, and appropriate use/resource use.

Gap Analysis

Overview – Consideration of gap analyses conducted by the MAP for the National Quality Forum (NQF), or by other organizations,[xx] is an important factor in the development of the draft MDP. As the draft MDP evolves through public comment and subsequent updates, CMS intends to enhance the number and utility of reportable clinical quality measures relevant to all specialties (and thereby all MIPS EPs) for scoring under the MIPS quality performance category.

Strategic Approach – CMS will conduct a comprehensive, systematic gap analysis of the existing measure portfolio to address gaps in measure domains (e.g., patient safety, care coordination, appropriate use) where there is demonstrable variation in performance by providers; gaps in types of measures applicable to medical specialties (see Appendix for a table of measure counts across medical specialties); measure gaps for clinicians in settings outside of traditional healthcare sites, including home care and telehealth; and gaps in measures applicable to people with certain healthcare conditions.

Applicability of Measures Across Healthcare Settings

Overview – MACRA requires the MDP to consider applicability across healthcare settings[xxi] in developing the measure portfolio for MIPS and APMs and 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 and using measures that may not be specific to a care setting.

[xix] Section 1848(s)(1)(D)
[xx] Section 1848(s)(1)(C)(i)
[xxi] Section 1848(s)(1)(C)(ii)

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] We will consider clinical practice improvement activities in future updates to the MDP.

Strategic Approach – No clinical practice improvement activities have yet been established under MIPS. In updates to the MDP, CMS will evaluate clinical practice improvement activities to identify concepts that could result in innovative approaches to new measure development at the national level to address gaps in measurement and clinical care.

Consideration for Electronic Specifications

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

Strategic Approach – CMS prioritizes electronic clinical quality measure (eCQM) development in a manner that ensures relevance to patients and the public, improves measure quality, increases clinical data availability, accelerates development cycle times, and drives innovation. CMS is championing eCQM development in the core areas of standards, tools, and processes. In addition, CMS will leverage existing relationships with QCDRs and promote integration with the measure development process.

Addressing Challenges in Quality Measure Development

Based on extensive experience in quality measure development, CMS has identified challenges that may arise in implementing the MDP, including:
- Engaging patients in the measure development process.
- Reducing provider burden.
- Shortening the period for measure development.
- Streamlining data acquisition for measure testing.
- Developing meaningful outcome measures.
- Developing patient-reported outcome measures (PROMs) and appropriate use measures.
- Developing measures that promote shared accountability across settings and providers.

Strategic Approach – CMS will implement collaborative approaches to address these challenges:

[xxii] Section 1848(s)(1)(C)(iii)
[xxiii] Section 1848(q)(5)(B)(ii)

- Focusing on integrating the voice of the patient, family, and/or caregiver in the measure development process.
- 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, provider, 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 (NTC) to facilitate measure testing.
- Prioritizing the development of outcomes measures, including PROMs, and appropriately risk-adjusting outcome measures.
- Supporting the development of health information exchange (HIE) to facilitate development of more care coordination and shared accountability measures.

Strategic Vision of the Measure Development Plan

This draft 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 patient-centered measure portfolio that addresses critical measure gaps; facilitates alignment across federal, state, and private programs; and promotes efficient data collection. 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 provider burden through the use of measures aligned across federal and private-payer quality reporting programs. Incorporating the patient and consumer voice throughout the measure development process will ensure that the measures will yield publicly reported results that patients and consumers can use to make informed decisions about their healthcare.

The resulting portfolio will evolve over time to include measures that:
- Follow the patient across the continuum of care for patient populations with one or more chronic conditions.
- Emphasize outcomes, including global outcome measures and population-based measures, balanced with process measures that are proximal 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).

- Apply to multiple types of providers, including clinical specialists, non-physician professionals, and non-patient-facing professionals.
- Are appropriate for low-volume (particularly rural) providers.
- Are adopted from other payment systems and applicable to physicians and other professionals.
- Align with other models and reporting systems—including with Medicaid, other federal partners, and the private sector—and are specified for multi-payer applicability.
- Account for the variation and diversity of payment models.
- Use data generated from EHRs, based as much as possible on existing provider workflows and inherently created as a by-product of providing clinical care.
- Incorporate broader use of QCDRs.
- Can produce results stratified by race, ethnicity, gender, and other demographic variables that are available to enable providers to identify and reduce disparities among vulnerable populations.
- Are suitable for public reporting on the CMS Physician Compare website.[xxiv]

We solicit comments from stakeholders on this approach as well as the prioritization of activities. The evolution and success of this plan will depend on collaboration and engagement with physicians and other stakeholders and across federal agencies to incrementally shift the focus of our national healthcare system to paying providers based on value rather than volume.

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

II. Introduction

MACRA[7,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 certain applicable provisions related to MIPS and to certain Medicare APMs.

To meet the requirements of the statute, CMS created this draft MDP. CMS solicits comments on this draft plan from the public, including healthcare providers, payers, consumers, and other stakeholders, through March 1, 2016.[xxvi] The final MDP, taking into account public comments on this draft plan, will be posted on the CMS website by May 1, 2016, followed by updates annually or as otherwise appropriate.[xxvii]

Background

The passage of the Affordable Care Act in 2010[8] was the catalyst for extensive reform of the U.S. healthcare delivery system. The law established the Health Insurance Marketplace to extend access to affordable care and provided strong incentives in publicly financed healthcare programs to connect provider payment to quality care and efficiency.

As the largest healthcare payer in the United States with more than 100 million consumers, CMS is at the forefront of our nation's healthcare delivery system. Building on the principles and foundation of the Affordable Care Act, 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. These are measurable goals to move the Medicare program and our healthcare system at large toward paying providers based on the quality, rather than the quantity, of care provided.[9]

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:

- Better Care,
- Smarter Spending, and
- Healthier People.[10]

[xxv] Section 1848(s)(1)(A), (5)
[xxvi] Section1848(s)(1)(E)
[xxvii] Section 1848(s)(1)(F), (3)(A)

Evolution of CMS Physician Quality Reporting Programs

To fulfill the measure development requirements of MACRA, CMS will draw on extensive experience in the development and use of quality measures from existing Medicare quality measurement and reporting programs, including the PQRS, VM, and EHR Incentive Program for EPs. 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 practices.[11] 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] PQRS was further extended and enhanced by legislation such as the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007,[xxix] the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008,[xxx] the Affordable Care Act of 2010,[xxxi] and the American Taxpayer Relief Act of 2012.[xxxii]

From 2007 to 2014, EPs 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. To satisfactorily report and earn an incentive, EPs were required to submit data on quality measures as individual EPs or through the Group Practice Reporting Option (GPRO) via one or more of the defined reporting mechanisms, including claims, qualified registries, EHRs, and the GPRO Web Interface. Beginning in 2015, incentives were replaced with negative payment adjustments for individual EPs and group practices that do not satisfactorily report data on quality measures or satisfactorily participate in QCDRs.

Value Modifier

The Affordable Care Act, section 3007,[xxxiii] mandated that CMS, beginning in 2015, apply a per-claim adjustment to payments for items and services under the Medicare Physician Fee Schedule (MPFS), based on prior performance (quality of care furnished compared with the cost of care); for 2015, CMS implemented this requirement for groups of 100 or more EPs. In 2016, VM is being further phased in by applying a payment adjustment to groups of physicians with 10 or more EPs. Beginning in 2017, the VM will apply to all physicians and groups of physicians. The phase-in of the VM will continue to evolve for 2018, as it also will apply then to MPFS payments made to certain non-physician EPs.

Meaningful Use and Electronic Health Records

As information technology (IT) and access to information became an increasingly large part of American culture and business, including healthcare, Congress passed legislation to smooth the transition for the creation, control, and dissemination of electronic medical information. The

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[xxviii] Section 101(b) of division B (Medicare Improvements and Extension Act of 2006) of the Tax Relief and Health Care Act (TRHCA).
[xxix] (Pub. Law 110-173) (MMSEA)
[xxx] (Pub. Law 110-275)
[xxxi] (Pub. Law 111-148)
[xxxii] (Pub. Law 112-240)
[xxxiii] Section 1848(p)(4)(B)(iii) of the Act

Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted as part of the American Recovery and Reinvestment Act of 2009[12] to promote the adoption and meaningful use of health IT.

The legislation required the Department of Health and Human Services (HHS) to establish programs that provide incentive payments to EPs who meaningfully use certified EHR technology, including reporting on clinical quality measures using EHRs. As of 2015, EPs who do not meet the requirements of the EHR Incentive Program and who do not qualify for a hardship exception receive a downward payment adjustment under the MPFS.

PQRS, VM, and EHR Incentive Program Consolidation

The PQRS, VM, and EHR Incentive Program programs have each played an important role in the early development of physician-based quality measurement and reporting in the Medicare program. However, to reduce provider burden, CMS seeks to optimize efficiencies through greater alignment across these programs, as stated in the 2015 Physician Quality Reporting Programs Strategic Vision:

> "While these efforts have been independently successful, CMS and its stakeholders—including patients, caregivers, and healthcare professionals—recognize that these programs can be optimized through greater alignment of measures, program policies, and program operations; deeper engagement with a variety of stakeholders; and expanded public reporting of provider performance."[13]

MACRA accelerates the alignment of measures, program policies, and operations by sunsetting the payment adjustments under the PQRS, VM, and EHR Incentive Program and establishing MIPS. MACRA also provides incentives to accelerate participation in APMs.

Measure Development Plan Purpose

The purpose of the MDP is to meet the requirements of the statute[xxxiv] and provide the strategic framework for the future of measure development for clinician quality reporting to support MIPS and APMs. The MDP builds on the existing set of clinician quality measures used in current CMS programs, prioritizing the development of outcome measures and measures that are relevant for specialty providers. CMS will expand and enhance existing measures to promote alignment and harmonization, while concurrently developing new (de novo) measures to fill measure and performance gap areas. We solicit public comment on specific areas and specialties to prioritize through MACRA funding over the next five years.[xxxv]

CMS is committed to working collaboratively with federal and state partners and private payers to create a set of aligned measures that will reduce provider burden. The MDP identifies CMS activities to promote alignment and harmonization (e.g., active participation in multi-stakeholder collaboratives and work groups whose purpose is measure alignment). The MDP also provides expectations for future measure development. CMS will require MACRA-funded measure

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[xxxiv] Section 1848(s)(1), (5)
[xxxv] Section 1848(s)(6)

developers to follow the general and technical principles included in Section III, which outlines the CMS Strategic Vision. We regard these as critically important to the long-term improvement and sustainability of measure development. The MDP also describes tools and resources that can facilitate the development of measures applicable to a wide variety of stakeholders.

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 support physicians who choose to participate in eligible APMs.

Merit-Based Incentive Payment System

MIPS evaluates each MIPS EP based on a composite performance score across four performance categories: [xxxvi]

- Quality
- Resource use
- Clinical practice improvement activities
- Meaningful use of certified EHR technology

The resulting composite performance score[xxxvii] is used to determine and apply a payment adjustment, which will begin in 2019.[xxxviii] Measures for use in the quality performance category are a specific focus of the MDP.[xxxix]

CMS will use the rulemaking process to establish an annual list of MIPS quality measures.[xl] This list will include, as applicable, quality measures from the PQRS, VM, and Medicare EHR Incentive Program.[xli,xlii] CMS will use the annual Call for Measures to request that eligible professional organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of quality measures and to identify and submit updates to the measures on such list.[xliii] CMS will begin to fill gaps in the measure set by developing additional measures using MACRA funding.[xliv]

Alternative Payment Models

In addition to establishing MIPS, MACRA provides for incentives to clinicians to participate in APMs that meet criteria specified in the law.[xlv] The MDP is required to include measures that could be used in these APMs[xlvi] and further requires quality measures used in APMs to be

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[xxxvi] Section 1848(q)(2)(A), (q)(5)(A)
[xxxvii] Section 1848(q)(5)(A)
[xxxviii] Section 1848(q)(1)(B), (q)(6)(A)
[xxxix] Section 1848(s)(1)(A), (5)(A)
[xl] Section 1848(q)(2)(D)(i)
[xli] Section 1848(q)(2)(D)(v), (vii)
[xlii] Section 1848(q)(2)(D)(v), (vii)
[xliii] Section 1848(q)(2)(D)(ii)
[xliv] Section 1848(s)(6)
[xlv] Section 1833(z)(1)(A)
[xlvi] Section 1848(s)(1)(A), (2)(A), (5)(B)

comparable to the quality measures used in MIPS.[xlvii] 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. Another important consideration for CMS and MACRA-funded measure developers is to understand the variation and diversity of payment models when identifying clinical quality measures for development.

Physician Compare

MACRA[xlviii] requires that performance and participation information under MIPS and APMs be made available for public reporting on the Physician Compare website.[14] The primary goal of Physician Compare is to help Medicare consumers make informed healthcare decisions.

MACRA Requirements for the Measure Development Plan

Section IV: Operational Requirements of the Quality Measurement Development Plan contains the Measure Development Plan Timeline and a plan for updates of the MDP. Section IV also discusses in detail the following requirements included in section 102 of MACRA that pertain to the MDP:

- Multi-payer applicability
- Coordination and sharing across measure developers
- Clinical practice guidelines
- Evidence base for non-endorsed measures
- Quality domains and priorities
- Gap analysis
- Applicability of measures across healthcare settings
- Clinical practice improvement activities
- Considerations for electronic specifications and QCDRs

[xlvii] Section 1848(s)(2)(A)
[xlviii] Section 1848(q)(9)

III. CMS Strategic Vision – Measure Development Priorities

CMS intends to build on existing quality measure sets to develop a patient-centered portfolio of measures. This portfolio of measures will address critical measure gaps; facilitate alignment across federal, state, and private programs; and promote efficient data collection, while also balancing individual and shared provider accountability. When publicly reported, these measures will help consumers make informed decisions regarding their choice of healthcare provider, facility, and services.. As the CMS portfolio of measures evolves to support the transformation of the healthcare payment system, CMS will seek early and frequent input from clinicians, payers, patients, caregivers, and stakeholders.

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. The MDP will also integrate recommendations from recent relevant publications and stakeholders.

The MDP leverages existing CMS measurement strategies, policies, and principles 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.

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 2015, articulates six goals to improve the quality of care in our healthcare system (Figure 3)[15]:

Figure 3: CMS Quality Strategy Goals

- Make care safer by reducing harm caused in the delivery of care
- Strengthen person and family engagement as partners in their care
- Promote effective communication and coordination of care
- Promote effective prevention and treatment of disease
- Work with communities to promote healthy living
- Make care affordable
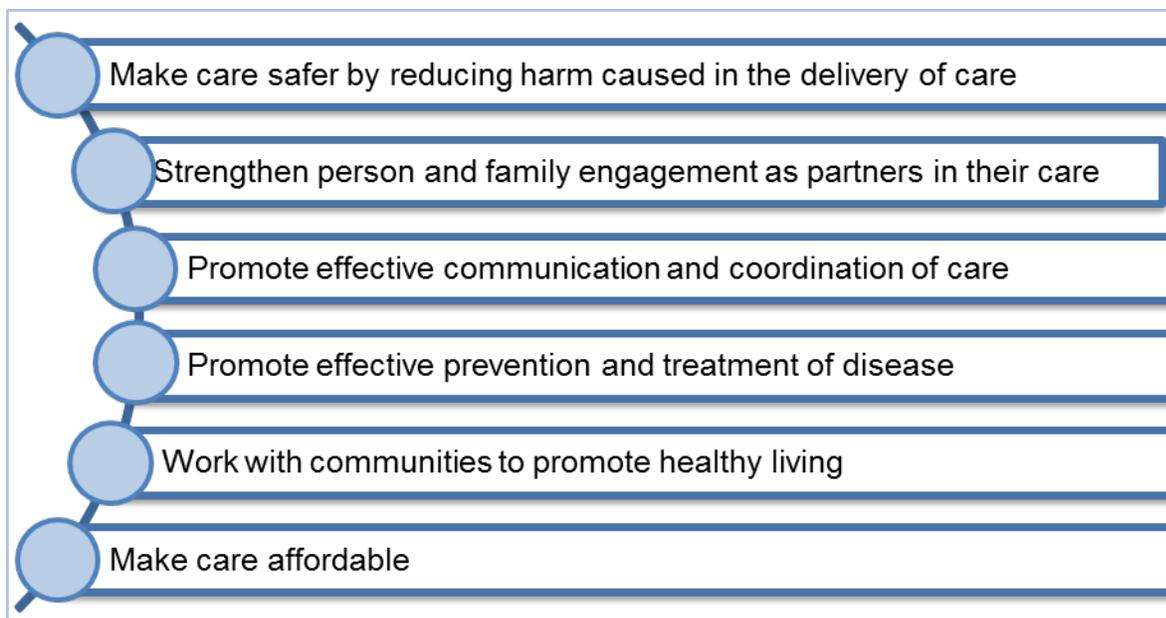
To succeed in its mission of improving healthcare outcomes, beneficiary experience of care, and population health while also reducing healthcare costs, the CMS Quality Strategy identifies four foundational principles that guide actions toward the achievement of these goals:

- Eliminate racial and ethnic disparities to achieve an equitable healthcare system.
- Strengthen infrastructure and data systems essential to a robust public healthcare 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.[16]

We intend to require measure developers with funding from section 102 of MACRA 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 healthcare. The MDP describes the approach to build upon existing physician quality reporting programs and the roles of quality measures in the transition to a value-based healthcare system. Aligning measure development with the goals of the CMS Quality Strategy will result in improved healthcare 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 physician quality reporting programs play an important role in advancing the goals of the CMS Quality Strategy. The Physician Quality Reporting Programs Strategic Vision[17] describes a long-term outlook for CMS quality measurement for physicians and other healthcare professionals and for public reporting programs. It promotes person-centered care and defines an approach to optimizing and aligning quality measurement to support informed decision-making by healthcare 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:

- CMS quality reporting programs are guided by input from patients, caregivers and healthcare professionals.
- Feedback and data drives 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.[18]

With the passage of MACRA, the strategic vision will bridge the transition from current programs, including PQRS, VM, and the EHR Incentive Program, into the future state of MIPS and APMs.

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, patient-centered measures that are suitable for consensus review and endorsement and developed in a transparent manner, incorporating 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. 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.

The MMS Blueprint underscores the commitment of HHS and CMS to coordinate with federal 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.[19]

The MMS Blueprint is updated at least annually, based on lessons learned and efficiencies gained during the development and implementation of measures.[20] 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. We intend to require organizations that develop measures for MIPS and APMs with funding from section 102 of MACRA to embrace these principles.

The general principles are guidelines to consider throughout the measure development process, in particular when identifying concepts for new measures. The technical principles should guide the development of measure specifications.

General Principles

1. Develop measures that explicitly align with the CMS Quality Strategy and its goals and objectives.
2. Align with other payers, including Medicaid, other federal partners, and private payers.
3. Address a performance gap where there is known variation in performance, not just a measure gap, and where there is important opportunity to advance population health.
4. Solicit patient/caregiver input in addition to provider input in the development of measures.
5. Develop measures in a rapid-cycle fashion in accordance with Lean principles.[xlix,21,22]
6. Collaborate with other developers freely and share best practices and new learning.
7. Reorient and align measures around patient-centered outcomes that span across settings—this may require different versions of the same measure (i.e., different cohorts but same numerator).
8. Focus on outcomes (including patient-reported outcomes, such as functional status after knee replacement), safety, patient experience, care coordination, and appropriate use.
9. Develop measures meaningful to patients/caregivers, providers, and the general public.
10. Monitor disparities in the delivery of care and unintended consequences of measure implementation, including overuse and underuse of care.
11. Focus on what is best for patients and caregivers for each decision made during the development life cycle.

Technical Principles

1. Develop a rigorous business case for an evidence-based measure concept—a critical first step in the development process.
2. Prioritize electronic data sources (EHRs, registries) over claims and chart-abstraction when possible, while maintaining measure reliability and validity.

[xlix] 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."

3. Define outcomes, risk factors, cohorts, and inclusion/exclusion criteria based on clinical as well as empirical evidence.
4. Judiciously select exclusions to ensure that measures capture as broad a patient population as possible and appropriate.
5. Adopt statistical risk adjustment models that account for differences in patient demographic and clinical characteristics across providers that may affect the outcome but are unrelated to the quality of care provided.
6. Develop risk adjustment models to distinguish performance between providers rather than predict patient outcomes.
7. Include measure stratification across different patient demographic characteristics to support the ability to monitor disparities and unintended consequences.
8. Harmonize measure methodologies, data elements, and specifications when applicable and feasible.
9. Strive to develop each measure with sufficient statistical power to detect and report statistically significant differences in provider performance based on available data sources.

Consideration of Recent Publications and Recommendations

In the development of this MDP, CMS considered recommendations from stakeholders and recent relevant publications, including an Institute of Medicine (IOM) report released in 2015, *Vital Signs: Core Metrics for Health and Health Care Progress.*[23] The report identifies a set of standardized measures to enable the healthcare system to work in a coordinated fashion toward a shared vision of America's healthcare. The IOM report notes that validated quality measures which meet many of the desired objectives do not currently exist; however, some measures do exist (e.g., childhood immunization rate, patient-clinician communication satisfaction) and there is potential to develop other needed measures under the focus areas of the broad IOM core metric categories. Such core measures could apply at varying levels, from state or national to a single community or organization. CMS shares this vision of an aligned healthcare system that uses measures across settings, applying at multiple levels of accountability, including global and population health.

CMS solicits comments with respect to how to use the measures identified by the IOM and approaches to develop remaining measures within the broad IOM categories that could be used in MIPS and in APMs to support the transformation of the healthcare delivery system from fee-for-service to population-based accountability systems.

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.[24] The report recommends phasing in mandatory participation in CMS quality measurement and quality improvement programs by rural providers, 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 providers, that use continuous rather than binary variables, and that have results expressed as ratios where the numerator is not part of the denominator. CMS will take these recommendations into

consideration in the implementation of the MDP and solicits comments with respect to strategies to ensure meaningful inclusion of rural and other low-volume providers in MIPS.

Measure Integration to Support MIPS and APMs

Through the 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 efficiency and cost reduction.

Existing measures from PQRS, VM, and the EHR Incentive Program will be the starting point for measures to be used in MIPS and APMs. Development of new measures funded under MACRA will begin to address gaps in the measure portfolio. The resulting portfolio will evolve to include measures that:

- Follow the patient trajectory across the continuum of care for patient populations with one or more chronic conditions.
- Emphasize outcomes, including global outcome and population-based measures, balanced with process measures that are proximal 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).
- Apply to multiple providers, including clinical specialists, non-physician professionals, and non-patient-facing professionals.
- Are adopted from other payment systems and are applicable to physicians and other professionals.
- Use data generated from EHRs, based as much as possible on existing provider workflows, and inherently created as a by-product of providing clinical care.
- Incorporate broader use of clinical data registries.
- Can produce results that are stratified by race, ethnicity, gender, and other available demographic variables to enable providers to identify and reduce disparities among vulnerable populations.
- Are suitable for public reporting on the CMS Physician Compare website.[1]
- 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 (particularly rural) providers.

Incorporating the patient and consumer voice throughout the measure development process will ensure that the measures are useful to support MIPS and APMs and meaningful to consumers.

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

IV. 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,[li] and CMS will build upon existing relationships to begin 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. These valuable partners and the public at large are encouraged to provide input during the public comment period on the MDP to continue to drive quality measure development efforts. In addition to the MDP, CMS released a Request for Information in the fall of 2015 as another means of receiving formal public and stakeholder input related to many of the MIPS and APM provisions of MACRA, including the quality measure requirements.

This draft MDP takes into consideration priority areas for future measures for MIPS that CMS identified during the 2015 Measures under Consideration cycle:[25]

> *"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"[lii]*

In accordance with MACRA requirements,[liii] we solicit comments on the draft MDP.

[li] 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)

[lii] Note: Appropriate Use measures are considered in their MDP as part of the Quality performance category of MIPS; however, Resource Use measures are outside of the scope of this MDP.

[liii] Section 1848(s)(1)(E), (4)

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."[liv]

Background – Quality measures currently in use by public and private payers include multiple measures for the same measure topic, which may be appropriate when the measures are complementary; however, some measures are duplicative with similar or partially aligned technical specifications. The resulting redundancy and variability creates an administrative burden for providers and health systems and, more importantly, limits opportunity for improved outcomes due to diffusion of focus for quality improvement.

Approach – CMS supports efforts to create aligned core measure sets across payers from both the private and public sectors that are meaningful to patients and providers and that will reduce administrative burden. 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 Measure Applications Partnership (MAP), the Core Quality Measures Collaborative, and the Health Care Payment Learning and Action Network (HCPLAN).

Measure Applications Partnership
Background – Section 3014(b) of the Affordable Care Act[26] 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. An important aspect of 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 Measure Applications Partnership (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

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

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 work groups 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.[27] MACRA specifies that the pre-rulemaking process and review by the MAP is optional for measures used for MIPS.[lv]

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 is completing 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.

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, providers, and payers. CMS is active in the Core Quality Measures Collaborative (the Collaborative), a work group convened in 2014 by America's Health Insurance Plans (AHIP), a national trade association representing the health insurance industry.

The Collaborative includes chief medical officers from AHIP member plans, leadership from CMS, and representatives from NQF, consumers and purchasers, and national physician organizations. 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)."[28]

Input from all stakeholders will assist the organizations participating in the Collaborative to identify the measure gaps to be filled and contribute to the focused development of new measures.

Approach – CMS will continue actively participating in the Collaborative and promote the development of core measure sets for quality reporting programs to support multi-payer

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

applicability. CMS will consider adopting core measures identified by the Collaborative through the rulemaking process.

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."[29] All stakeholders are invited to participate and leverage the opportunity to join work groups and learning sessions on increasing the adoption of APMs and other care delivery models.

The work groups 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. Work groups 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 consider strategies generated from the HCPLAN work groups related to quality measures to align measures in MIPS and APMs.

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."[lvi]

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 a quality measures task force across CMS divisions to develop recommendations focused on reducing duplication of efforts and eliminating inconsistencies in specifications.
- Partnering with the AHRQ to co-lead the Measure Policy Council (MPC), composed of representatives from federal agencies.[lvii] The MPC evaluates measures in use across

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[lvi] Section 1848(s)(1)(A)(ii)
[lvii] 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

HHS, creates consensus around harmonized core measure sets for high-priority areas, and coordinates future measure development.

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

- Maintaining a comprehensive Pipeline/Measures Under Development Inventory that catalogs measures in progress and 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.
- Maintaining a measure developer library where materials created during the measure development process can be shared.
- Hosting information sessions facilitated by the MMS Contractor and open to all measure developers.
- Supporting the Electronic Clinical Quality Improvement (eCQI) Resource Center, which provides a one-stop source for the most current resources to support electronic clinical quality measurement and improvement. [30]

To support the development of eCQMs, CMS established cross-cutting measure development initiatives that actively engage developers and stakeholders in key areas:

- Clinical quality measure process improvement events (e.g., Lean Kaizen), which bring together stakeholders involved in measure development to identify inefficiencies in the development of eCQMs 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 eCQM development for CMS programs. The group achieves this mission through a consensus approach and dissemination of information to stakeholders across CMS and HHS[lviii] and broadly within the healthcare and health IT industry.
- Biweekly Electronic Measures Issues Group (eMIG) forums and webinars[31] composed of representatives from CMS, measure developers, contractors, EHR vendors, and other federal agencies[lix] 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.

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).

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

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

- Online feedback mechanisms and forums where stakeholders such as measure developers, stewards, providers, and implementers can view and comment on potential errors, misalignments, feasibility, and improvements to existing measures as well as those under development.

Collectively, these communication channels promote knowledge sharing of best practices, tools and resources, experiences, and individual contractor measure development products. CMS will build upon this successful, established foundation of collaboration within the measure development community and will actively seek additional perspective and input from federal agencies such as the departments of Defense and Veterans Affairs (VA).

Such initiatives have improved communication and knowledge sharing across measure developers within CMS and HHS and contributed significantly to consistency and standardization in clinical quality measure development processes and specifications. However, enhancing existing activities and promoting broader participation are critical to achieving ongoing and successful collaboration among organizations developing measures for MIPS and APMs.

For example, QCDRs currently develop measures for clinical practices, but measure developers do not always have access to these measures during environmental scan processes. In addition, QCDR measures may not be part of the MAP process and are not required to go through consensus-based endorsement processes. They may receive variable quality assurance checks and testing prior to deployment. To support broader consideration and integration of QCDR measures in MIPS, CMS will promote knowledge sharing across measure developers and QCDRs to foster consistent use of the standardized processes documented within the CMS MMS Blueprint.

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."[lx]

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

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

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[lx] Section 1848(s)(1)(A)(iii)
[lxi] Section 1848(s)(2)(B)(ii)(II)

evidence and an assessment of the benefits and harms of alternative care options."[32]

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 remain an important part of quality measurement. Performance on process measures is directly under the control of the professional, so improvement may be more readily achievable.

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 many as three out of four Americans aged 65 years and older[33]—may require more complex care decisions than guidelines aimed at a single condition adequately address.[34,35]

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 three-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 healthcare delivery. CMS will ensure that measure developers continue to include members from clinical specialty societies and other healthcare 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.[36] 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*).[37]

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.*[38] The framework is a set of new and previously identified principles for addressing issues related to multiple chronic conditions in the guideline development process.[39] CMS will continue to work with specialty societies and other guideline developers to provide data addressing multiple chronic conditions.

We solicit comments on these recommendations as well as new approaches to aligning clinical practice guidelines with measure development.

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."[lxii]

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. Review and evaluation of evidence is an important component of developing the business case; however, developers should also quantify the performance gap or variation in performance in order to demonstrate that there is room for improvement. Measures that are based on clinical guidelines or other evidence, but for which there is no room for improvement because most providers already perform highly, 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.[40] For measures that are not consensus-endorsed, CMS will ensure that each measure is evidence-based and in alignment with NQF requirements for the consensus review process. Unless 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 patients across genders, races, and ethnicities.

CMS will also continue to require that measure developers submit a well-crafted business case for a measure concept that includes a thorough review of evidence in addition to a demonstration

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

of the extent to which provider performance varies and the potential impact of the measure in terms of lives saved and cost saved. Measure concepts for which there is minimal variation in performance or for which the evidence base is weak will receive much lower priority for development. In addition, 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.

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:[lxiii]

"(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:[lxiv]

''(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 facilitate tracking and assignment of measures, address gaps, and drive quality improvement.

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*[41] (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.

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 healthcare when measures are publicly reported.

[lxiii] Section 1848(s)(1)(B)
[lxiv] Section 1848(s)(1)(D)

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. Since 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 proposes to include efficiency and cost reduction as a quality domain in addition to the five quality domains identified in MACRA (clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention).[lxv]

Additionally, MACRA prioritizes outcome measures, patient experience measures, care coordination measures, and measures of appropriate use of services, such as measures of overuse. Opportunities for 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 they can be measures of patient-centered outcomes of disease conditions, including PROMs and measures of functional status (topics that have been prioritized in MACRA). 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 where there are important gaps in performance and for topics that are important to both patients and providers. Outcome measures (including PROMs and measures of functional status), intermediate outcome measures, and measures assessing diagnostic skills and adherence to clinical practice guidelines are measure development priorities for MIPS and APMs. We solicit comments and suggestions for development of measures in this domain.

Safety

Background – Safety measures reflect the safe delivery of clinical services in all healthcare 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 healthcare, such as an adverse event. Safety measures also address complications of procedures, treatments, or similar interventions during healthcare delivery. Measures of inappropriate use that has the potential to 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 healthcare system or a healthcare 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 healthcare 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.[42]

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

Therefore, ample opportunities exist to identify performance gaps and to develop additional measures in the Safety domain.

Approach – CMS will develop safety measures for EPs 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 consider for development include medication errors, complications from procedures, and all-cause harm in the outpatient or ambulatory setting. We solicit comments and suggestions for development of measures in this domain.

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 are identified as a priority topic for measure development in section 102 can be used to promote shared accountability among providers contributing to the care of a patient. For example, members of a patient care team for a person with type 2 diabetes mellitus might include a primary care physician, podiatrist, endocrinologist, pharmacist, and nutritionist. 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* used in the Hospital Inpatient Quality Reporting Program and the *All-Cause Unplanned Admissions for Patients with Heart Failure* measure used in the Medicare 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 patient moving between both providers 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 providers to facilitate the appropriate delivery of healthcare services are also in this domain.

Approach – The MIPS performance category of clinical practice improvement activities includes a subcategory of care coordination.[lxvi] 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 providers, and use of remote monitoring or telehealth.[lxvii] When evaluating and/or funding measure development specific to CPIAs submitted for telehealth, CMS and measure developers must be cognizant of the services Medicare covers in this area.

[lxvi] Section 1848(q)(2)(B)(iii)(III)
[lxvii] Section 1848(q)(2)(B)(iii)(III)

To promote improved collaboration across providers, 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 care physician to the specialist. Expansion of this measure is being considered 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 to link information between care settings. 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*,[43] 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). We solicit comments and suggestions for development of measures in this domain.

Patient and Caregiver Experience

Background – The domain of patient and caregiver experience includes measures that focus on the potential to improve patient-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 healthcare team and collaborative partners with providers 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 healthcare.

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 healthcare providers and address topics for which patients are the only or best source of information, such as whether the patient thought he/she was treated respectfully.[44] Many of the CMS patient experience surveys are part of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) family of surveys.[45] 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."[46]

Approach – 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 patient experience surveys based on stakeholder feedback to incorporate additional topics that are important to patients and families/caregivers (e.g., patient knowledge, skill, and confidence for self-management and whether the provider acted in accordance with the patient's preferences; participation of family members in care discussions or electronic communications; accurate documentation of family members who are authorized decision-makers). CMS will balance the need to obtain important information from patients with the need to minimize patient and provider burden in implementing and responding to the surveys. CMS is interested in the development and use of specialty-specific surveys in MIPS and APMs. We solicit public comment regarding the utility of specialty-specific patient experience surveys and

whether such surveys exist and are in use in Medicaid or the private sector—through either plans or providers.

Population Health and Prevention

Background – 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.[lxviii] In addition to measuring the use of preventive services at the individual patient level, CMS will consider 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. 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. 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. We solicit comments and suggestions for development of measures in this domain and for attributing measure results to specific EPs and/or EP groups.

Efficiency and Cost Reduction

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 healthcare resources or inefficiencies in healthcare delivery.

Measures of appropriate use of services, including measures of overuse, are identified as a priority for measure development under MACRA. The 2015 PQRS includes 16 measures in this domain out of the 254 measures in the set.[47] 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 healthcare 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.[48]

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

Approach – CMS considers appropriate use measures to be a very high priority for MIPS and APMs. CMS will ensure that measure developers consider evidence-based practices related to overuse. For example, 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 patients in their efforts to make informed and effective healthcare 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.[49] 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.

As providers 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.

CMS seeks comments from the public as to relevant topic areas for this category of measures. CMS is also aware of concern about the unintended consequence of underuse of services once overuse measures are implemented and seeks comments from the public on mitigation strategies, including the use of balancing measures and suitable exclusions.

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. . . ." [lxix]

Background – This draft 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 outcomes, cost and resource use measures, appropriate use measures, care coordination measures, measures focused on specialty care, special patient populations, and patient safety measures) as a critical program objective for physician quality measurement programs. These objectives establish a framework for the future direction of measurement development. [50]

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

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

recommended adding outcome measures and clinically relevant measures for specialties/subspecialties that do not currently have clinically relevant measures.[51]

As the draft MDP evolves through public comment and subsequent updates, CMS intends to increase the number of reportable clinical quality measures relevant to all specialties (and thereby all MIPS EPs) in order to be scored under the MIPS quality performance category. A table in the Appendix counts current measure coverage for eligible professionals across medical specialties. We will provide additional analysis in the final Measure Development Plan to identify the number of clinical quality measures that are reportable for MIPS and high-priority gaps. We will include a discussion of utility identified through public comment.

Approach – The strategic approach for gap analyses related to MIPS and 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, and affordable care. Measure concepts identified to fill these gaps should emphasize patient-reported outcomes and processes closely linked to outcomes, as well as clinical outcomes. Clinically relevant measures for physician specialties/subspecialties, including non-patient-facing professionals,[lxx] should also be identified.

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 providers, where there is demonstrable variation in care and therefore opportunity for improvement. To improve measure coverage across all EPs, CMS intends to evaluate gaps in measures for specialties and subspecialties, as reporting ability can vary significantly across different types of clinicians.

Applicability of Measures Across Healthcare Settings

The MACRA requirement –
> "In developing the draft plan under this paragraph, the Secretary shall consider . . . whether measures are applicable across healthcare settings."[lxxi]

Background – MACRA requires this draft MDP to consider the applicability of measures across healthcare settings. Applicability of measures across settings can be achieved by:
- Adapting and aligning measures originally developed for another setting or level of the healthcare 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, physician group, and physician level, using aligned specifications/definitions.
- Using facility-level measure rates for clinicians who practice in a facility.

[lxx] Section 1848(q)(2)(C)(iv)
[lxxi] Section 1848(s)(1)(C)(ii)

- 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 patients with multiple chronic conditions). MACRA authorizes the Secretary to use certain measures from non-physician payment systems for purposes of the quality and resource use performance categories.[lxxii] CMS will assess options for allowing facility-based EPs to use their facility's performance on quality metrics (e.g., metrics in the Hospital Value-Based Purchasing Program for hospitalists) to apply to the quality domain for their MIPS composite performance score in certain circumstances—for example, where facilities have a strong incentive to hold EPs accountable for meeting facility performance goals. CMS will seek comment on such options through the rulemaking process.

CMS also seeks comments from the public regarding which measures in use in other healthcare settings may be appropriate for modification at the physician or other healthcare professional level and what types of measures would be most appropriate for use across a health system that spans multiple settings of care.

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."[lxxiii]

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)[lxxiv,lxxv]:

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)

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

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[lxxii] Section 1848(q)(2)(C)(ii)
[lxxiii] Section 1848(s)(1)(C)(iii)
[lxxiv] Section 1848(q)(2)(B)(iii)
[lxxv] Section 1848(q)(2)(B)(iii)

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.

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, providers 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, and this could inform patient-reported outcome measure development. CMS solicits comments from the public on how the use of such tools and other clinical practice improvement activities could inform future quality measure development.

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."[lxxvi]

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.

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 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 and timely data and/or feedback reports.

Figure 4: eCQM Stakeholder Engagement

Potentially, the broader use of eCQMs could simplify the process of capturing, comparing, and evaluating performance results at the

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[lxxvi] Section 1848(s)(2)(B)(ii)(I)
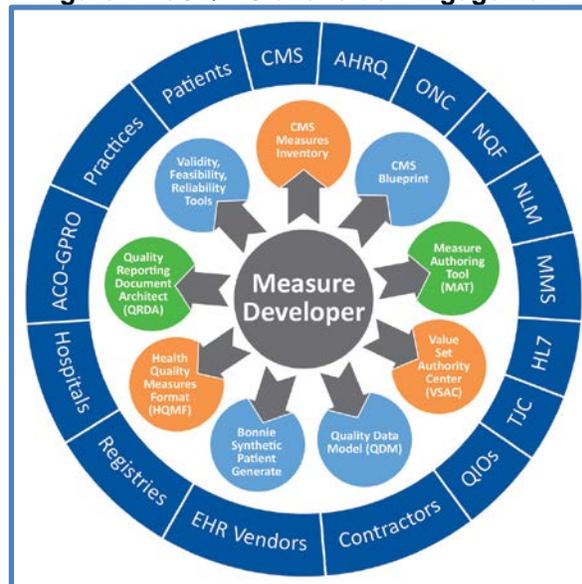
individual and population health levels. However, the development and implementation of eCQMs is a complex process that requires close coordination, communication, and collaboration across multiple internal and external stakeholders to be successful, as shown in Figure 4.

In selecting measures for development for MIPS and APMs, CMS must consider whether proposed measures appear viable for electronic specification. Specifications for eCQMs should be derived from a feasible set of electronically captured data elements and a realistic clinical workflow. The stakeholder community should aid in test implementations and evaluation of the data elements, workflow, and measure specification itself. In turn, measure developers must use these data to evaluate industry readiness to implement proposed eCQMs.

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. Through the earlier and broader use of clinical data and common data models, CMS can provide measure developers with the standardized data elements necessary to support successful eCQM implementation without adding the long delays and costs associated with site recruitment, data acquisition, and field testing by individual measure developers.

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, and 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 Test Bed (NTB) was conceptualized at the February 2013 Lean Kaizen event, based on stakeholder analysis of current eCQM testing processes. The goal of the NTB was to expand and improve measure testing by incorporating earlier and more frequent engagement across stakeholders. The National Testing Collaborative (NTC) was formed in 2014 to build upon the framework of the NTB and is continuing to recruit participants to support measure testing efforts. A key future-state goal of the NTC is to serve as an innovation hub to the measure development community through crowdsourcing and the conducting of low- to no-cost eCQM pilot and implementation testing. The NTC also intends to serve in a matchmaking capacity to identify, vet, and pair prospective participants with measure developers to promote and support early engagement in the development process. Other initiatives include the development of marketing materials and templates to support broader NTC awareness and participation.[52]

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 an eCQM 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).[53]

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 includes data assets to both build and test measures for future endorsement consideration to drive outcome-based healthcare measurement.[54]

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

Approach – CMS intends to prioritize the development of eCQMs in a manner that ensures patient relevance, 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 eCQM 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 eCQM ecosystem. CMS works closely with ONC and standards developing organization communities such as Health Language 7 (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 eCQM 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 eCQM development, CMS recognizes the need to continually evaluate the usability of the current standards to support long-term eCQM 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 (e.g., Clinical Quality Language [CQL], 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 work group, 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 eCQM measure development:
    - Measure Authoring Tool (MAT) – Allows measure developers to author computable eCQMs specifications based on the current program versions of eCQM standards.[55]

- 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.[56]
- Bonnie – Validates eCQM logic to ensure that the measure is specified as intended through patient scenario testing.[57]
- JIRA – Provides a central Web-based application for triaging and responding to stakeholder feedback on eCQM annual update measure releases.[58]

- **Processes**: To drive improvement in eCQM 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 eCQM development cycle (i.e., the "future state"). Multiple process improvements have resulted from these events, including a more streamlined and aligned eCQM annual update process, the formalization of external logic and value set review processes, and the establishment and use of the eCQI Resource Center for eCQM developers. CMS will continue promoting the broader adoption and use of process improvement in MACRA-funded clinical quality measure development efforts. 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.

The continuing evolution of these standards, tools, and processes will streamline eCQM development. We solicit comments on how to collaborate further with specialty societies and measure developers in the broader use of the tools and standards for eCQM development.

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.*"*[lxxvii]

''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.''[lxxviii]

"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.''[lxxix]

[lxxvii] Section 1848(s)(1)(E)
[lxxviii] Section 1848(s)(1)(F)
[lxxix] Section 1848(q)(2)(D)(iv)

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 physician measurement programs, anchor the time frame available for measure development. The MAP pre-rulemaking activities are not required under MIPS,[lxxx] 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 is dependent upon many factors (e.g., type of measure, availability of data, data source). 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,[lxxxi] 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.[lxxxii] The time frame to prepare the manuscript and adhere to the peer-reviewed journal's requirements will need to be carefully considered to meet the timeline and requirements of MACRA.

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).

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.[lxxxiii] 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.[lxxxiv]

[lxxx] Section 1848(q)(2)(D)(ix)
[lxxxi] Section 1848(q)(2)(D)(v)
[lxxxii] Section 1848(q)(2)(D)(iv)
[lxxxiii] Section 1848(q)(2)(D)(i)(I)
[lxxxiv] Section 1848(q)(1)(B)

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."[lxxxv]

"(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"[lxxxvi] and

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

Approach – CMS will maintain the MDP and post updates annually or otherwise as appropriate on the CMS.gov website, where the final MDP will be posted. The annual report will include a summary describing measure development activities conducted during the year, newly identified measure gap areas,[lxxxviii] 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.

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."[lxxxix]

Approach – The annual 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

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[lxxxv] Section 1848(s)(3)(A)
[lxxxvi] Section 1848(s)(3)(B)(iv)
[lxxxvii] Section 1848(s)(3)(B)(v)
[lxxxviii] Section 1848(s)(3)(B)(iv)
[lxxxix] Section 1848(s)(3)(B)(ii)

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.
    - Outcome (other than PROM): Measures that assess the results of healthcare which patients experience. They include endpoints such as well-being, ability to perform daily activities, or 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 healthcare 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 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."[xc]

Approach – The annual update 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.[xci] The summary will include the total number of measures; the count of measures by type, including process measures, PROMs, other outcome measures, and

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[xc] Section 1848(s)(3)(B)(iii)
[xci] Section 1848(s)(3)(B)(iii)

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 one, two, and three 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.

Figure 5: Timeline for Pre-Rulemaking and Rulemaking Activities and Annual Updates
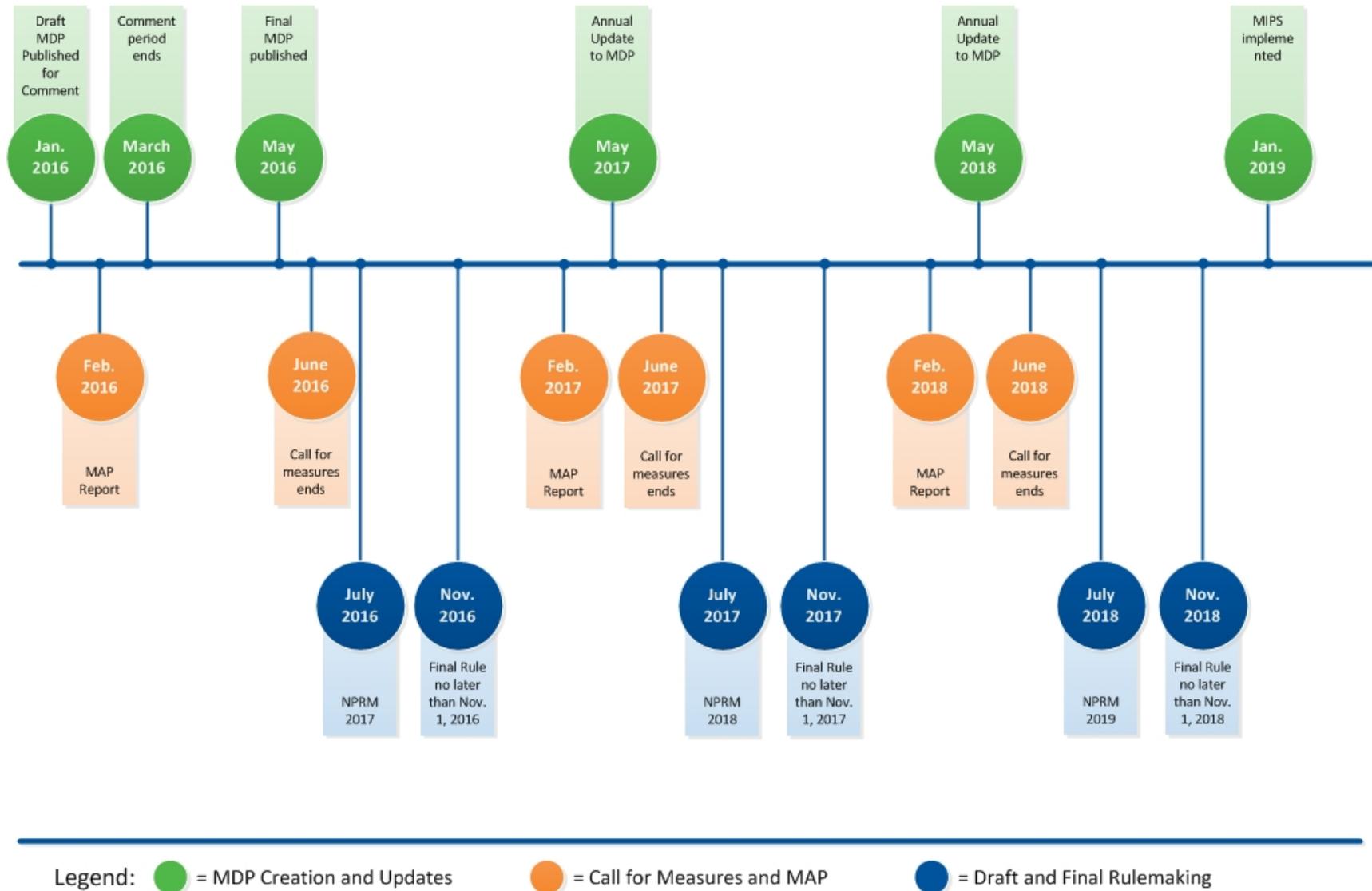
V. Challenges in Quality Measure Development and Potential Strategic Approaches

This section describes the critical challenges to implementing the MDP, specifically related to measure development, and identifies potential strategic actions to address these challenges. We solicit comments from the public on the viability of these approaches as well as any additional or alternative recommendations.

Engaging Patients in the Measure Development Process

Background – The development of patient-centric measures is dependent on having the voice of the patient, family, and/or caregiver incorporated during the measure development process. Involving patients and caregivers allows them to share personal stories about their healthcare experiences and how these experiences relate to measure development priorities.

In 2012, CMS began to require measure developers to include one or more patients/caregivers in the measure development process.[59] Challenges with patient engagement include recruitment of patients; patients and caregivers needing additional support and orientation to participate fully; and patients feeling intimidated when surrounded by subject matter experts having 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 the patient/caregiver engagement process include:

- Conducting outreach to patients through patient organizations and other organizations that focus on engaging patients (e.g., PatientsLikeMe, Patient-Centered Outcomes Research Institute) and condition-specific patient organizations (e.g., the Arthritis Foundation, the Cancer Support Center).
- Screening candidates for background relevant to the measure development project.
- Preparing patients/caregivers by orienting them to the measure development process and patient/caregiver role during measure development and establishing a mentor on the measure development team.
- Educating meeting facilitators/moderators on how to engage patients.

Reducing Provider 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 providers and care teams. In addition, measures that are not aligned increase the burden to report because of variation in measure specifications and submission requirements.

Strategic Approach – CMS strives to minimize provider burden by collecting data that are part of the existing clinical workflow. CMS also prioritizes the development of measures based on data from EHRs that can decrease the data collection burden while maintaining measure validity.

CMS collaborates with EHR vendors and frontline providers during the measure development process to maximize the use of existing clinical workflows to capture information required for quality measurement. Additionally, collecting data directly from the patient or caregiver can supplement provider-generated data and allow broader data mining for a given measure. CMS has also been working closely with private payers and other stakeholders to develop consensus around core sets of quality measures that would be used by all payers. CMS will continue to promote the development of measure sets that are aligned across payers and settings by ensuring that developers collaborate across public and private sectors.

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.[xcii] The impact of this new requirement on the time frame of measure implementation remains to be determined. An extensive time frame 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. We seek comment through this MDP on ways to efficiently move proposed measures through the peer-reviewed journal process. CMS is especially interested in comments from both peer-reviewed medical journals and measure developers about integrating this step into existing workflows.

Strategic Approach – CMS has 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 of the process. 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. In addition, improved functionality and integration of the MAT and the VSAC tools has reduced measure development time. CMS will promote the continued adoption of Lean principles to reduce waste throughout the measure development process and use established forums for dissemination. CMS intends to streamline the interactions and transitions between members of the measure development community.

To further reduce the timeline for the measure development process, CMS will facilitate cross-developer transparency and knowledge sharing through expanded use of the CMS measure developers library and forums. The Web-based library stores documents and work products from measure development projects across CMS. 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.

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

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 and promote the formation of a National Testing Collaborative (NTC). As part of the NTC, CMS is investigating the potential to implement overarching agreements with clinical data registries, data repository vendors, health plans, and provider groups to make administrative and clinical data more accessible and less costly to acquire. Use of these data would inform early measure specification development, enhance testing of measure reliability and validity, and facilitate risk adjustment of outcome measures. In turn, costs and time for developers to acquire data would be reduced, and the number of providers participating in measure testing would be expanded.

Identifying and Developing Meaningful Outcome Measures

Background – Two key challenges to 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 provider performance for outcome measures requires careful consideration and evaluation of associated patient risk factors (e.g., age, comorbidities). Yet the development of risk adjustment models is constrained by limited sample sizes and data availability.

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. Vulnerable patient populations will be represented in this effort to capture the unique challenges facing these populations, which lead to disparities in health and healthcare. Patient/caregiver input will be balanced with the provider/clinician perspective and with evidence-based research.

Specific to risk adjustment, CMS is participating in an NQF pilot project to evaluate incorporation of sociodemographic factors into risk-adjustment models. In addition, ASPE 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.

Furthermore, 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 also increase the availability of data to identify and test data elements for incorporation into risk-adjustment models.

Developing PROMs and Appropriate Use Measures

Background – MACRA prioritizes the development of patient experience, care coordination, appropriate use, and patient-reported outcome measures.[xciii] 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[60] into performance measures based on data contained within EHRs. 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 as well.

Strategic Approach – To initiate the development of PROMs, CMS introduced several "building block" measures as part of the Medicare EHR Incentive Program.[61] For example, process measures capturing pre- and post-surgical functional status assessment for hip and knee replacement surgery and congestive heart failure were developed.[62] 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 may also leverage emerging initiatives such as the joint HHS and U.K. National Health Service cooperative related to PROMs.[63] We solicit comments on ways to capture patient-reported data in a manner that does not create undue burden (e.g., minimizing overall patient paperwork, forms, etc.).

For appropriate-use measures, CMS plans to emphasize the concepts in the Choosing Wisely campaign, which has expanded to include more than 300 recommendations from 70 organizations.[64] CMS will also 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 HHS eCQM National Testing Collaborative, 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 EHR Incentive Program for EPs assess individual or group practice-level performance rather than holding more than one provider type accountable for the care of patients. As payment systems 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. Developing measures of shared

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

accountability requires improved provider coordination across care settings and interoperable health information exchange among a variety of healthcare 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 HIE 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 HIE through longstanding relationships with the National Committee on Vital and Health Statistics and industry partners such as the Workgroup for Electronic Data Interchange and the Council for Affordable Quality Healthcare. To encourage HIE adoption more broadly across settings, CMS proposes to[65]:

- Enable HIE, where possible, in support of state-led delivery and payment reform through federal and state partnerships.
- Encourage interoperability across states' electronic information infrastructures, including Medicaid and state survey agencies.
- Continue stakeholder collaboration to facilitate the adoption and use of health IT standards and interoperability requirements.

To promote improved collaboration across providers, 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 care physician to the specialist. Expansion of this measure is being considered to include specialist reports to primary care physicians.

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 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 EPs serving the Medicare population.

Organizations developing measures under CMS contracts 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 CMS Quality Strategy serves as a compass to guide the measure development efforts. The Physician Quality Programs Strategic Vision lays a foundation for applying these tenets to MIPS and to APMs as they evolve. The MMS Blueprint directs measure developers to ensure that measures are evidence-based, meaningful to patients, reliable, and valid and developed in a transparent manner that engages stakeholders. CMS general and technical principles provide guidance throughout the measure development process. The MDP will be updated annually or as otherwise appropriate to report progress, including activities conducted during the year, newly identified measure gaps, and challenges encountered.

CMS is committed to reducing provider burden through the use of measures aligned across federal and private-payer quality reporting programs. We stress harmonization of data elements and specifications among measure developers, whose cooperation and sharing are essential to creating aligned measures. Toward that end, we also intend to leverage the optional pre-rulemaking process and MAP review for MIPS and to participate with other stakeholders in efforts that promote measure alignment. This draft MDP acknowledges the associated challenges and identifies opportunities for measure developers to share information to reduce duplication of efforts.

The successful implementation of the MDP depends on collaboration with multiple stakeholders to develop measures that are meaningful to patients and providers and can be used across payers and healthcare 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. The resulting patient-centered portfolio will be a key lever of delivery system reform, furthering the aims of Better Care, Smarter Spending, and Healthier People.

Appendix – Reportable Measures by Specialty

Table 1: 2016 Physician Quality Reporting System (PQRS) Measure Counts – by Specialty and National Quality Strategy Domain

ABMS Specialties	Number of Measures							
	Total Applicable 2016 PQRS Measures[1,2]	Outcome[1,2]	Effective Clinical Care[1,2]	Patient Safety[1,2]	Communication and Care Coordination[1,2]	Person and Caregiver-Centered Experience and Outcomes[1,2]	Efficiency and Cost Reduction[1,2]	Community/ Population Health[1,2]
Allergy and Immunology	26	4	11	1	2	0	5	7
Anesthesiology	5	1	1	2	2	0	0	0
Colon and Rectal Surgery	14	5	4	5	3	1	1	0
Dermatology	11	1	1	2	5	1	1	1
Emergency Medicine	21	3	10	0	0	0	10	1
Family Medicine	97	18	55	7	8	6	8	13
Medical Genetics and Genomics	0	0	0	0	0	0	0	0
Internal Medicine	85	14	52	6	8	5	5	9
Neurological Surgery	10	2	3	3	2	1	1	0
Nuclear Medicine	4	0	0	0	1	0	3	0
Obstetrics and Gynecology	25	4	8	8	3	1	0	5
Ophthalmology	16	9	9	2	3	2	0	0
Orthopaedic Surgery	14	4	1	6	3	4	0	0
Otolaryngology	18	2	1	1	4	3	8	1

ABMS Specialties	Number of Measures							
	Total Applicable 2016 PQRS Measures[1,2]	Outcome[1,2]	Effective Clinical Care[1,2]	Patient Safety[1,2]	Communication and Care Coordination[1,2]	Person and Caregiver-Centered Experience and Outcomes[1,2]	Efficiency and Cost Reduction[1,2]	Community/ Population Health[1,2]
Pathology	8	0	5	0	3	0	0	0
Pediatrics	29	4	15	1	2	2	3	6
Physical Medicine and Rehabilitation	21	6	5	4	10	1	0	1
Plastic Surgery	5	0	0	3	1	1	0	0
Preventive Medicine	32	2	13	4	4	1	0	10
Psychiatry and Neurology	37	12	19	5	8	1	1	3
Radiology	28	6	8	5	7	3	5	0
Surgery	16	12	5	9	1	1	0	0
Thoracic Surgery	24	10	11	8	1	1	3	0
Urology	16	3	4	6	2	2	1	1

[1]The 2016 PQRS measure implementation guide and related list of 2016 measures can be found at:
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html.
Please click on the URL and accept the terms and conditions.

[2]The universe of measures that a given specialty can report can be broader than the counts explicitly listed, as many specialists report on cross-cutting measures that may be applicable to their scope of practice (e.g., smoking cessation). There may also be instances in which a given ABMS subspecialty has fewer measures to report than the specialty count listed.

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
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
CQL	Clinical Quality Language
EHR	electronic health record
EP	eligible professional
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
GPRO	Group Practice Reporting Option
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*
HIE	health information exchange
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009
HITSC	Health Information Technology Standards Committee
HL7	Health Language 7
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
MPFS	Medicare Physician Fee Schedule
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
PCORnet	The National Patient Centered Clinical Research Network
PQRS	Physician Quality Reporting System
PROM	patient-reported outcome measure
QCDR	qualified clinical data registry
QDM	Quality Data Model
QRDA	Quality Reporting Document Architecture
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
U.K.	United Kingdom
VM	Value Modifier
VSAC	Value Set Authority Center

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