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MEDICAL SOCIETY

# Patient-Reported Outcome Measures: Current State and MMS Principles

## BACKGROUND

The Massachusetts Medical Society (MMS) adopted the MMS Principles on Patient Reported Outcome Measures at its April 2018 House of Delegates meeting. This report provides background for these 13 principles.

The MMS wholeheartedly supports the use of Patient-Reported Outcome Measures (PROMs) as quality improvement tools that can both improve care delivery and enhance patient engagement. PROMs are validated questionnaires that turn a symptom or any other patient-reported outcome (PRO) into a numerical score.<sup>1</sup> With PROMs, providers can use numbers to describe, for example, how much a knee replacement helps a patient walk. PROMs can help quantify symptoms, functional status, and mental health.<sup>2</sup> While being a powerful new tool to measure quality, PROMs are still being validated and risk-adjusted for many clinical, social, and demographic factors — processes that could take years to complete.

Knowing this, the MMS does not support the use of Patient-Reported Outcome Measures for quality incentive payments and instead advocates for leaving them in the quality improvement domain until they mature. Payment to providers by health plans and other organizations to implement and perform PROMs will help expedite their implementation, use, and maturation as a quality tool.

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<sup>1</sup>Food and Drug Administration. Guidance for Industry Patient-Reported Outcomes Measures. December 2009.

<sup>2</sup>Safran. Promoting the Use of PROMs: Early Experiences from BCBSMA Presentation. September 2017.

## 1. Introduction

Changing market forces have placed a premium on “quality,” causing a shift from fee-for-service reimbursement to value-based payment models.<sup>3</sup> Under the 2015 Medicare Access and Children’s Health Insurance Program Reauthorization Act, providers will be evaluated on quality and cost efficiency and receive adjusted reimbursement for their performance. However, there is not much evidence that performance metrics and incentives have resulted in better health outcomes.<sup>4,5</sup> Patient-reported outcome measures (PROMs) may fill this critical gap in the measure set for global budget contracts. PROMs are validated questionnaires that turn a symptom, or any other patient-reported outcome (PRO), into a numerical score.<sup>6</sup> With PROMs, providers can use numbers to describe, for example, how much a knee replacement helps a patient walk. PROMs can help quantify symptoms, functional status, and mental health.<sup>7</sup> Although current performance reimbursement metrics do not integrate PROMs, numerous clinicians are concerned with whether and how PROMs will play a part in value-based payment reform in the future. Their perspective is that PROMs as a quality improvement tool is supportable but tying reimbursements to the reported outcomes is not.

## 2. Current Clinical Performance Measures

Clinicians seek to provide better value in health care and want to define what constitutes a good outcome. Currently, there are many clinical performance measures, but they often miss this overarching goal.<sup>8</sup> Most measures capture the process of care, such as drawing labs or starting medication. But these measures fail to capture the reason that patients are seeking care — to improve their symptoms. Additionally, current outcome measures, such as mortality and hospital readmission, are important but are also multifactorial. These measures are not completely under the control of the provider.

Many current outcomes measures vary little across providers and fail to differentiate between bad, good, and exceptional care. These measures focus on diagnoses rather than quality across the spectrum of care. Measures that span the spectrum of care report upon symptoms, patient experience, functional status, pain, well-being, daily activities, mental health, and quality of life. Lastly, many areas of care, including specialty, post-acute, and end-of-life, are not covered by these existing outcome measures.<sup>9</sup>

## 3. The Promise of PROMs

The current era of health care is defined by quality, accountability, measurement, and risk bearing. Quality measurement can be achieved by also creating metrics most important to patients. PROMs can be used to demonstrate variation by provider — or modality — to discover value.<sup>10</sup> Many medical conditions have relevant PROs, such as mental health, heart failure, stroke, prostate and colon cancer, asthma, and inflammatory bowel disease.<sup>11</sup> Using validated tools to measure PROs for these

<sup>3</sup>Wagle. Patient-Reported Outcome Measures Presentation. March 2016.

<sup>4</sup>Lee. Effect of Nonpayment for Preventable Infections in US Hospitals. *NEJM*. 2012.

<sup>5</sup>Jha. The Long-Term Effect of Premier Pay for Performance on Patient Outcomes. *NEJM*. 2012.

<sup>6</sup>Food and Drug Administration. Guidance for Industry Patient-Reported Outcomes Measures. December 2009.

<sup>7</sup>Safran. Promoting the Use of PROMs: Early Experiences from BCBSMA Presentation. September 2017.

<sup>8</sup>Lavallee. Incorporating Patient-Reported Outcomes into Health Care to Engage Patients and Enhance Care. *Health Affairs*. April 2016.

<sup>9</sup>Ibid.

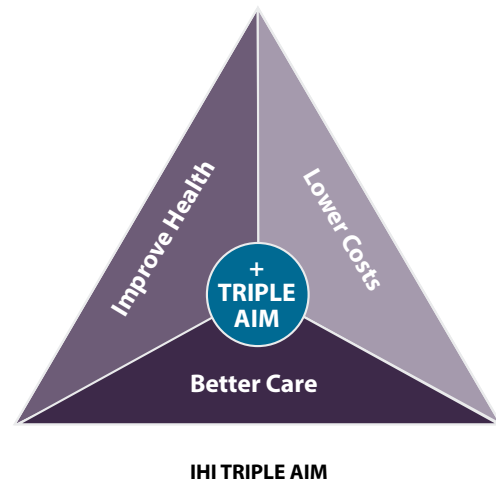
<sup>10</sup>Wagle. Implementing Patient-Reported Outcome Measures. *NEJM Catalyst*. September 2017.

<sup>11</sup>Wagle. Patient-Reported Outcome Measures Presentation. March 2016.

conditions makes the data interpretable and actionable. The data can then be compared across providers and institutions. This additional data can save time and enable deeper, more personalized care when PROs are embraced.<sup>12</sup>

#### 4. PROMs and the Triple Aim

The goals of the Triple Aim are to (i) improve the patient experience, (ii) improve the health of populations, and (iii) reduce the per capita cost of health care. As mentioned previously, PROMs provide an opening to improve communication for patients and clinicians and to enable the delivery of patient-centered and equitable quality care, consistent with the Triple Aim. PROMs may also help cut costs, mainly when used to detect unmet needs, such as communication of incapacity to pay for medications. The clinician could counter this problem by prescribing a more cost-effective medication regimen. Moreover, there has been a suggestion to develop the Triple Aim to the Quadruple Aim, which would incorporate increasing career satisfaction and decreasing stress experienced by the health care workforce.<sup>13</sup> PROMs may bolster this additional goal by promoting patient-centered care and engaged teams of clinicians.



PROMs were devised to assist patient-centered care, making PROMs a natural solution to methodically tackle many of the requirements of a patient-centered medical home (PCMH). From a very concrete standpoint, PROMs can be used to meet the requirements of the National Committee for Quality Assurance (NCQA) PCMH 2014 standards within Standard 4: Plan and Manage Care, as well as in Standard 6: Measure and Improve Performance. Regular integration of PROMs may help practices meet these standards for primary or renewed NCQA PCMH acknowledgment.<sup>14</sup> PROMs permit systematic assessment of patients' main concerns and can be employed as instruments to meet the NCQA PCMH 2014 standards.

#### 5. Payer Perspective on PROMs

Health authorities and payers recognize the importance of patient perspectives and PROMs in health care decision-making. However, given the comprehensive diversity of PRO endpoints included in clinical programs and differences in the timing of PROM data collection, the role of PROM data in reimbursement decisions requires further research and characterization.

A 2017 study by Brogan et al. found that PROM data may assist in differentiating treatments, particularly after clinical progression, in oncology.<sup>15</sup> The report also found that payers worldwide identify high-quality PRO data as an important factor of their decision-making process and anticipate the mounting importance of PROMs over the next 5 to 10 years.<sup>16</sup>

<sup>12</sup>Wagle. Implementing Patient-Reported Outcome Measures. *NEJM Catalyst*. September 2017.

<sup>13</sup>Careyva. Setting the Agenda for Patient-Centered Care. *J Community Medicine & Health Education*. April 2016.

<sup>14</sup>Ibid.

<sup>15</sup>Brogan et al. Payer Perspectives on Patient-Reported Outcomes in Health Care Decision Making: Oncology Examples. *J Managed Care Spec Pharm*. February 2017.

<sup>16</sup>Ibid.

Public payers are also approaching PROMs implementation to improve patient outcomes and control costs. For example, under the Comprehensive Care for Joint Replacement program, now a voluntary program by CMS, participating providers will need to monitor for quality and improve value in patient care. CMS will link each hospital's incentive or penalty to a composite quality score based on three measures, including a PROM linked to functional status and pain management.<sup>17</sup>

*“PROM data may assist in differentiating treatments”*

Additionally, it is now mandated by CMS that dialysis facilities ask patients to complete the In-Center Hemodialysis Survey Consumer Assessment of Healthcare Providers and Systems semiannually and the Kidney Disease Quality of Life 36 annually.<sup>18</sup> In addition, patients are evaluated for depression and pain once a year.

## 6. PROMs Abroad

Collection of “patient-generated health data” (or PROMs) has been taking place in Europe for quite some time. For instance, in the Netherlands, PROMs are mandated for certain types of patients and conditions, such as behavioral health, orthopedics, and neurology.<sup>19</sup> To address this mandate, electronic tools automatically choose survey instruments from a validated library and administer them at the suitable intervals to patients founded on their ICD diagnosis code.

Recently, the worth of PROMs in Europe has begun to be studied. Preliminary results show that PROMs do support more evidence-based decision-making and value-based care delivery. Additionally, PROMs allow providers to better provide care in the right setting (tertiary hospital versus community clinic).<sup>20</sup> Results have shown that obtaining PROMs through traditional, rudimentary approaches, such as paper-based exchanges between providers and their patients during the visit, were less standardized and less useful than online approaches.<sup>21</sup>

## 7. PROMs at Home: Blue Cross Blue Shield of Massachusetts

Blue Cross Blue Shield of Massachusetts (BCBSMA) recognized that PROMs fill critical gaps in the measure set for global budget contracts, such as the Alternative Quality Contract. In 2013, BCBSMA provider networks collaboratively chose priority conditions for PROMs implementation. In selecting initial areas of focus, the providers focused on areas of high prevalence, cost, and utilization.<sup>22</sup> Joint degeneration, primarily hip and knee, and depression were identified as areas in need. Additionally, these conditions, which were conducive to measuring and monitoring changes in functional status, have validated PROM instruments already in place that providers can use to initiate participation among their patients.

The results of PROMs implementation among members with joint degeneration or depression were promising. BCBSMA members who reported with a score greater than nine on a baseline PHQ-9 (an instrument for screening, diagnosing, monitoring, and measuring the severity of depression) were re-administered the PHQ-9 at a 12-month follow-up visit. The PHQ-9 severity category saw substantial improvement among those with mild and moderate depression at baseline.<sup>23</sup> However, among severe and moderately severe patients, more than half see no change after 12 months.

<sup>17</sup>Ayers. Successful Use of Patient Reported Outcomes in Bundled Patient Contracts. *Becker's Hospital Review*. 2016.

<sup>18</sup>Finkelstein. Time to Rethink Our Approach to Patient-Reported Outcome Measures for ESRD. *CJASN*. 2017.

<sup>19</sup>Butterfield. Health Data — Patient Report Outcomes Measure: Europe Shows Us the Way. *PSQH*. 2014.

<sup>20</sup>Ibid.

<sup>21</sup>Ibid.

<sup>22</sup>Safran. Promoting the Use of PROMs: Early Experiences from BCBSMA Presentation. September 2017.

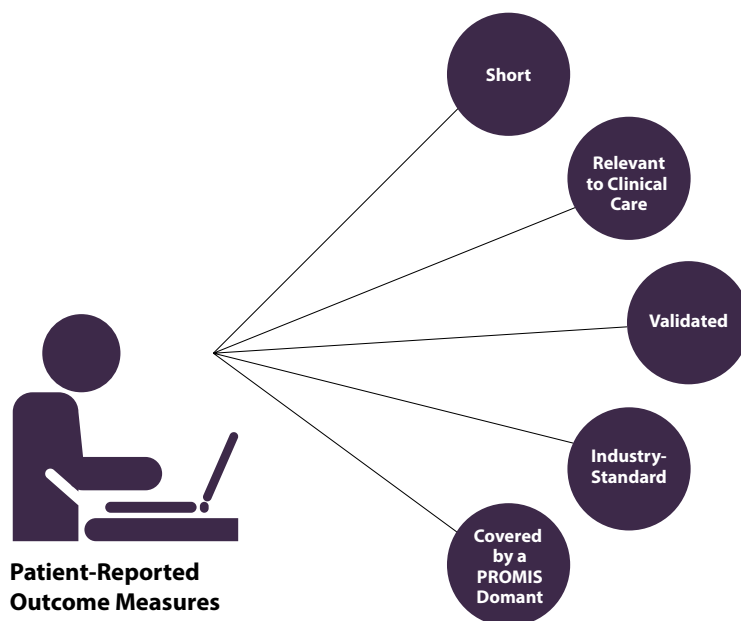
<sup>23</sup>Ibid.

For hip and knee replacement, change scores in pain, symptoms, activities of daily living, sports and recreation, and quality of life were calculated before and after the surgery. All respondents reported decreased pain and symptoms, increased ability to perform daily activities and to participate in sports and recreation, and improved quality of life after the surgery.<sup>24</sup> BCBSMA used these scores to compare provider groups based on these metrics for educational and improvement purposes.

To provide context, BCBSMA shared its framework for how to progress through three stages of implementation with PROMs. Phase 1 is paying for adoption, data sharing, and shared learning. Phase 2 is beginning to use the collective information to inform clinical treatment choices and shared decision making with patients. Phase 3 is accountability uses. BCBSMA acknowledged there is much deep empirical work needed before these (or other outcome measures) are ready for phase 3. They also note that a great deal of good is accomplished through diligent and inclusive work on phases 1 and 2 and therefore embrace the framework and the work associated with each phase. Plans call for the BCBSMA to fully discuss phase 2 results with provider networks.

### 8. How to Select PROMs

Consensus on a PROM to measure is challenging but not impossible. There are certain criteria to select a PROM. The PROM should be short, relevant to clinical care, validated, industry-standard, and covered by a PROMIS (Patient-Reported Outcome Measurement Information System) domain.<sup>25</sup>



There is an emerging consensus to use PROMIS. PROMIS is a free, National Institutes of Health-sponsored system.<sup>26</sup> The goal of PROMIS is to develop, validate, and standardize item banks to measure PROs relevant across common medical conditions. PROMIS measures are standardized, allowing for assessment of many PRO domains, including pain, fatigue, emotional distress, physical functioning, and social role participation, based on common metrics that allow for comparisons across domains, across chronic diseases, and with the general population.

<sup>24</sup>Ibid.

<sup>25</sup>Patient-Reported Outcome Measurement Information System (PROMIS). [www.healthmeasures.net/explore-measurement-systems/promis](http://www.healthmeasures.net/explore-measurement-systems/promis).

<sup>26</sup>Ibid.

## 9. Implementation of PROMs

To implement PROMs successfully, robust collection requires engaging patients, frontline staff, and clinicians on a functioning platform. Ideally, the technology platform would work seamlessly for all three parties, requiring secure, integrating, real-time processing. However, many systems that are collecting PROMs are still doing so manually with paper surveys and follow-up.

### Patients

To reach the patient and receive complete results, the survey must get into the hands of the patient. To do this, providers must use a platform that is relatively easy and intuitive to use. Using a tablet, for example, is a convenient way to reach patients regardless of age.<sup>27</sup>

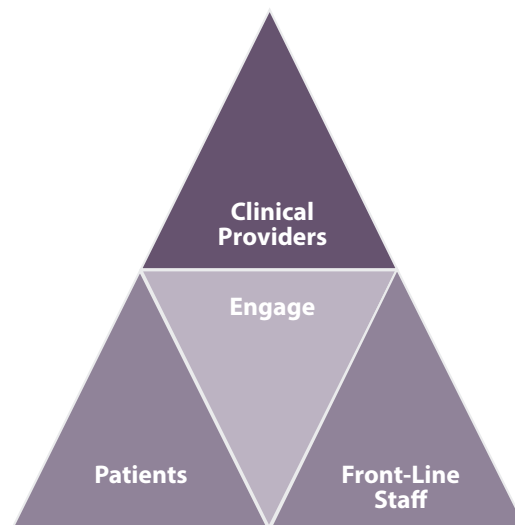
Most importantly, patients must be assured that the provider to improve clinical care is using the results. The first time, patients must be told in a believable way that the provider will see these results. Subsequent times, patients must see it used by the provider.

### Front-Line Staff

PROMs must improve or minimally impact workflow for frontline staff. To avoid making PROMs “one more thing” to be done, there must be no variability or confusion for staff to decide who to give PROMs to. Making all pre-visit activities digital is a possible solution to automate the process as much as possible.

An administrative champion is key to the successful implementation of PROMs. This champion is responsible for creating a PROMs mandate, engineering the workflow, and holding all staff accountable.<sup>28</sup>

Providers must communicate the imperative to effectively collect PROMs to the frontline staff. In addition to the administrative champion, clinicians must convey the importance of PROMs to clinical care.<sup>29</sup>



### Clinical Providers

Lastly, but most importantly, providers must enthusiastically embrace PROMs. This will require a process that takes careful planning and implementation. Health systems and/or practices need to remove administrative tasks, such as meaningful use, screening requirements, and symptoms documentation, so that providers will have more time to analyze and incorporate PROMs into daily clinical care, enabling a deeper connection with patients. Additionally, providers can progress with the use of PROMs for more than patient care: PROMs could be used over time to demonstrate value and comparative effectiveness.

<sup>27</sup>Ibid.

<sup>28</sup>Ibid.

<sup>29</sup>Ibid.

## 10. Cost of Implementation

The implementation of technology to collect PROMs can be costly. For example, a large teaching hospital or medical center that is aiming to create an institutional custom-built program will face many challenges, including a need for IT experts, provider content knowledge and interest, and ongoing resources for program maintenance. IT experts, clinician champions, and administrators require salary support. A recent article in *NEJM Catalyst* details the proposed costs associated with a custom-built PROMs collection platform.<sup>30</sup>

However, there are many benefits to a custom-built collection platform. Data display can be altered and customized for greater analysis. Scoring of PROMs tools and updates can also take place in real time. Sharing data with other groups and practices throughout the institution is easier as well. Controlling data collection means that integration into the workflow is smoother and can be altered more easily.

## 11. Barriers to Adopting PROMs

There are both technological and operational barriers to adopting and implementing PROMs.<sup>31</sup> The data are best submitted through electronic means to administer surveys, calculate scores, and trend results. This requires an electronic patient platform that works with a patient portal and is also integrated into the EHR. In turn, all these platforms must work seamlessly for patients and physicians to want to use them.

Operationally, instituting PROMs increases demands on all participants in the health care system.<sup>32</sup> Physicians already feel as if they are awash in data and cannot add another step into their schedule. Human connection is what brought many clinicians into medicine and many clinicians feel that adding technology into the relationship is taking away that connection.

## 12. Unintended Consequences of Reimbursing PROMs

PROMs focus on precisely defined, measurable aspects of a patient's health and health care. Policies, such as the compulsory use of PROMs<sup>33</sup> and financial or accreditation incentives for achieving PROMs benchmarks, may encourage providers and systems to alter their behaviors and policies. In a practice with severe time and resource constraints, implementing PROMs may mean less time and resources go to other priorities<sup>34</sup> that might be more critical to patient care. For example, a study in the United Kingdom contends that a nationwide initiative linking financial incentive to rapid primary care access, as measured by a single patient-reported experience measure, may have resulted in an extensive decrease in provider-specific continuity in primary care.<sup>35</sup> By incentivizing providers to guarantee swift access to any provider within their organization as a means of ensuring patient satisfaction, organizations may have sacrificed continuity of care, which is crucial for many high-risk patients.<sup>36</sup>

Additionally, many clinicians register concern that PROMs may affect or bias provider decision-making. For instance, will providers choose not to operate on or treat higher risk patients out of fear of a poor PROM? From the patient side, will athletes choose to forgo a procedure because of unrealistic expectations?

<sup>30</sup>Baumhauer et al. *NEJM Catalyst*. January 2018.

<sup>31</sup>Wagle. Patient-Reported Outcome Measures Presentation. March 2016.

<sup>32</sup>*Ibid.*

<sup>33</sup>Wolpert. Uses and Abuses of PROMs. *Adm Policy Ment Health*. 2014.

<sup>34</sup>Estabrooks. Harmonized Patient-Reported Data Elements in the EHR. *J AM Med Inform Assoc*. 2012.

<sup>35</sup>De Lusigna. The Development of Primary Care Information Technology in the United Kingdom. *J Ambul Care Management*. 2008.

<sup>36</sup>*Ibid.*



Providers also worry that, if PROMs collection becomes widespread, patients will feel overwhelmed with constant surveys, leading to survey fatigue. If patients feel the surveys are overwhelming or inconvenient, they may begin to complete the survey haphazardly or incompletely, jeopardizing the provider's reputation or, potentially, reimbursement.

Finally, many providers believe that as virtual survey tools become available and replace verbal, face-to-face contact between provider and patient, the patient-provider relationship will become even more depersonalized.

### 13. Feasibility of PROMs Implementation

Since PROMs are in their infancy, many health care providers have numerous concerns surrounding the implementation of PROMs. For instance, what agency will pay for the implementation of PROMs? Will there be recommended standards for administering PROMs and reducing measurement error?

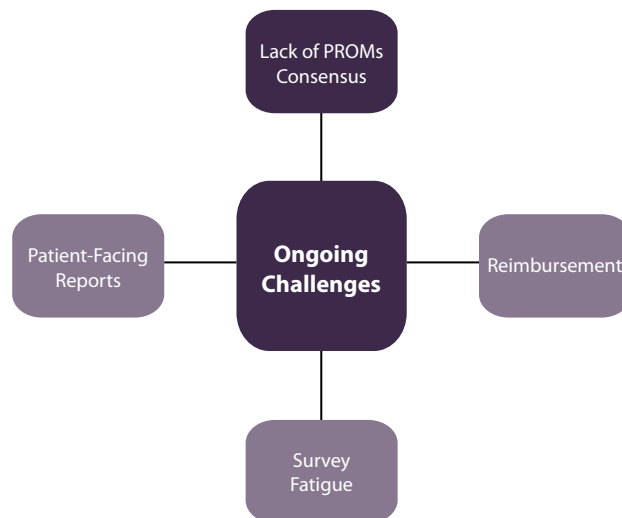
Major EHRs have integrated patient portals where customizable questionnaires can be formed. However, health care providers need to know if PROMs that are already in place will be copyrighted. If so, will there be a charge for each use or a licensing agreement? Additionally, will certain PROMs measurement tools be available in a public domain?

### 14. Ongoing Challenges

Despite progress, ongoing challenges remain for the widespread implementation of PROMs and collection platforms.

#### Lack of PROMs Consensus

There is a lack of consensus for which PROM is best for various conditions. With the development of PROMIS and the International Consortium for Health Outcomes Measurement (ICHOM), there is a push toward the development of a single set of measures for a diagnosis. ICHOM has produced over 10 standard sets of PROs covering approximately 35 percent of the global burden of disease, including cataracts, prostate cancer, lower back pain, coronary artery disease, Parkinson's disease, stroke, hip and knee osteoarthritis, depression and anxiety, and lung cancer.<sup>37</sup> Currently, ICHOM is establishing systems of hospitals around the globe, to measure, benchmark, and perform PRO comparisons.<sup>38</sup> All this data will translate into further learning about what truly matters to the patient.



<sup>37</sup>Kelley. International Consortium for Health Outcomes Measurement. *BioMed Central*. 2015.

<sup>38</sup>Ibid.

## Reimbursement

Currently, PROMs are being implemented with a pay-for-participation model. However, with a push for movement toward value-based care, PROMs may eventually be used as a performance measure for reimbursement programs. Researchers and providers must develop a technique to risk-adjust for clinical, social, and demographic patient characteristics.<sup>39</sup>

## Survey Fatigue

If collection of PROMs becomes widespread, there must be strategies to avoid bombarding patients with a multitude of surveys. Reaching patients conveniently, while respecting their privacy and security, is a priority to avoid survey fatigue.<sup>40</sup>

## Patient-Facing Reports

Lastly, visualizing PROM data for patients and generating patient-facing reports on how this data are being used is critical for implementation and continued use of PROMs. After initial surveys, it is essential that patients see the data used by providers in subsequent clinical care.<sup>41</sup>

The exercise of public reporting of PROMs will also require careful consideration and input from physicians.

## 15. Conclusion and Recommendation

PROMs are a valid quality improvement and patient engagement tool. However, since PROMs implementation remains in its infancy and many factors, including patient compliance, expectations, social, and demographic aspects, and other risk adjustment can skew the outcomes, PROMs results should not be used to compare providers or outcomes for payment. The following principles were adopted by the MMS in April 2018.

### MMS Principles on Patient-Reported Outcome Measures (PROMs)

1. **Quality improvement activities are an integral part of health care delivery today.**
2. **PROMs are expected to play a more prominent role in improving and assessing performance by including the patient's assessment of the comparative effectiveness of different treatments, in part because of the growing emphasis on patient-centered care and value-based payment designs.**
3. **In the era of patient-centered care and motivation toward high-quality care, active implementation of patient-reported outcome tools (Internet, automated phone systems, phone app, etc.) is a logical next step toward achieving these goals, as long as those tools are accessible to those less comfortable with technology and account for the cost of implementation.**
4. **Implemented correctly, PROMs have the potential to improve patient-physician communication, increase symptom management and control, and increase patient and physician satisfaction.**

<sup>39</sup>Wagle. Patient-Reported Outcome Measures Presentation. March 2016.

<sup>40</sup>Ibid.

<sup>41</sup>Ibid.

5. When selecting a PRO to measure, the PROM should be short, relevant to clinical care, validated, industry-standard, and may be covered by PROMIS (Patient-Reported Outcomes Measurement Information System) domain.
6. Routinization of this type of two-way communication between the provider and the patient, through use of the electronic tools (as noted in principle 3), may serve to improve care in ways that advance the Triple Aim's design to (i) improve patient experience, (ii) enhance the health of populations, and (iii) reduce per capita cost of health care.
7. Health plans, payers, and other health care improvement organizations should reimburse for quality improvement implementation activities, especially PROMs, as these measures require technology support, workflow adjustments, and continuous improvement.
8. However, PROMs should not be used to benchmark the performance of providers in different practices, specialties, or geographic locations against one another, potentially influencing payers to link reimbursement to evidence of the effectiveness of their treatment. Instead, these quality improvement tools should be used to advance quality of care within a specific practice or medical center, improve provider-patient communication, and enhance understanding of expectations. Because PROMs are in their infancy, more research needs to be done to understand how to risk-adjust these measures and how to account for realistic and unrealistic patient and provider expectations.
9. In addition to the need for added research on risk adjustment and patient expectations, PROMs performance results should not be linked to reimbursement due to many other factors, including patients' compliance, demographic, and social factors, which influence outcomes and create bias. Because PROMs results are not completely attributable to the physician's performance alone, providers find it hard to reconcile reimbursement and the often-imprecise nature of PROMs results. Rather, PROMs should be used to complement quality improvement activities.
10. The need for demographic (age, sex, etc.) risk adjustment to make PROMs more valuable should be emphasized both at the clinical level for providers to be able to use PROMs appropriately but even more so at the health plan level if PROMs are to be used for any type of provider comparison or payment.
11. Although the goal of medicine is to improve health outcomes for patients, using PROMs results for physician accountability and reimbursement requires additional research and validation of measures and outcomes.
12. The MMS strongly advocates for monitoring national dialogue surrounding PROMs, including a focus on their validity and usefulness in clinical practice.
13. The MMS will keep the membership informed of identified issues with relevant implemented patient-reported outcome measures and advocate strongly, by whatever means appropriate, for the growth and maturation of PROMs as a quality improvement tool and against implementation of inappropriate or inadequate PROMs, and against the use of PROMs results for quality incentive payments. (HP)

In summation, the MMS wholeheartedly supports the use of Patient-Reported Outcome Measures (PROMs) as quality improvement tools that can both improve care delivery and enhance patient engagement. Knowing the PROMs are in their infancy, the MMS does not support the use of Patient-Reported Outcome Measures for quality incentive payments and instead advocates for leaving them in the quality improvement domain until they mature.



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