

Public Comment Summary Report

Project Title:

Patient Understanding of Key Information Related to Recovery From an Outpatient Surgery or Procedure

Dates:

The Call for Public Comment ran from March 15, 2022, to April 11, 2022.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Services Corporation (YNHHSC) Center for Outcomes Research and Evaluation (CORE) to develop a patient-reported outcome performance measure (PRO-PM) for the effective transfer of clinical information from provider to patient after a procedure or surgery (hereafter, Information Transfer PRO-PM). The contract name is Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Period 2. The Contract number is HHSM-75FCMC18D0042, Task Order HHSM-75FCMC19F0002.

The aim of the Information Transfer PRO-PM under development is to assess patients' perceived understanding of information provided to them that is critical to their recovery process following an outpatient procedure or surgery. It evaluates, from the patient perspective, whether patients had and understood the clinical information they needed for their recovery process. CMS may consider the measure for use in the quality measurement of hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs).

As part of its measure development process, CORE requested interested parties to submit comments on the candidate measure. The primary goal of the call for public comment, as part of measure development consistent with CMS' measure development guidance, was to gather comments from a broad range of stakeholders on the measure under development. These stakeholders included technical experts, providers, patients, purchasers, and the public at large. CORE invited interested parties to comment on the following topics: survey instrument, measure specifications, measure cohort, survey implementation, and future considerations such as the usability and use of the measure. This report summarizes the comments we received and our responses.

Information About the Comments Received:

We solicited public comments by posting on CMS' Public Comment webpage and sending email notifications to:

- CMS listserv groups.
- The project's national Technical Expert Panel (TEP) and Patient Workgroup.
- Emails to relevant stakeholders and stakeholder organizations, including:
 - Business and consumer advocacy organizations.
 - Condition-related registries.
 - Electronic Health Record vendors.
 - Healthcare quality-focused organizations.
 - Insurance and purchaser organizations.

- National professional associations and clinician societies.
- Patient advocacy groups and patient safety organizations.
- Quality improvement and measurement organizations.
- Research organizations.
- State societies.
- Topic knowledge-related organizations.

In total, 15 organizations submitted comments on the Information Transfer PRO-PM. Of the commenters, nine were medical associations or professional societies; three were healthcare quality-focused organizations; two were healthcare systems; and one was a quality measurement-related organization.

Stakeholder Comments:

General Stakeholder Comments:

We received comments on various aspects of the measure specifications and implementation. Comments focused on the measure concept and methodology, including the survey instrument, risk adjustment, measure cohort, survey implementation, and future considerations.

Most commenters were supportive of the development of the measure. Commenters noted the measure concept captures the patient perspective on the information related to their recovery, which is noted as a measurement gap, and it is critical to engage patients in the outcomes of their procedures and surgeries. Several commenters offered constructive feedback on the measure, including suggestions to improve the survey instrument's language, conduct more robust measure testing to address concerns with limited variation in measure scores, and considerations for risk-adjustment variables. Other comments focused on known implementation issues like survey fatigue, data collection burdens, methods of survey administration to patients, and barriers related to Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs). Three commenters were critical of the measure. They were concerned it is duplicative of the Outpatient and Ambulatory Surgery (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey recently finalized by CMS for mandatory reporting beginning with Calendar Year (CY) 2024 for HOPDs and CY 2025 for ASCs. These commenters were critical of continued measure development and expressed concerns with implementation issues identified above (survey fatigue, data collection burden, and implementation barriers). They encouraged reconsidering the gap in measurement and measure testing before deciding on measure implementation. For more details about the commenters' concerns, see the summaries of the comments received and our responses below. The verbatim comments are also included in [Appendix A starting on page 12](#).

Measure-Specific Stakeholder Comments:

General

Six commenters supported the development of the Information Transfer PRO-PM for use in HOPDs and ASCs.

- One commenter expressed support for the measure and suggested it be used as an alternative to the current ASC-11 measure (Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery). One commenter noted the measure has the potential to effectively inform providers and practices of their impact and stated engaging patients in the improvement of their health care experience is key to creating more patient-focused processes. Two commenters noted support for the development of the measure. One commenter noted that the measure would fill a gap in measurement that remains despite the creation of CAHPS measures.

Response: We appreciate the commenters' support for this PRO-PM and agree that it will be beneficial to both patients and facilities.

Four commenters had concerns with the evidence supporting the measure concept.

- One commenter noted that the information provided by an ASC to patients around their procedure or surgery is concise and patient centered because it is tailored to each patient's needs rather than being a standard set of instructions generated by a computer program. One commenter referred to a study collecting data on colonoscopy and esophagogastroduodenoscopy procedures in which 93% of patients reported that they received discharge instructions (uncited). Another commenter was concerned with the lack of evidence to support poor performance from ASCs in providing adequate discharge information as well as the lack of testing being conducted within ASCs. One commenter noted there is a lack of clinical support.

Response: We recognize and appreciate the commenters' feedback and ASCs' commitment to providing their patients with written instructions tailored to each patient's needs and acknowledge that there is disagreement in the literature about how frequently outpatient facilities routinely provide patients with high quality information about their procedure or surgery. We clarify the goal of this measure is not to capture whether a patient received the information or not, but rather to capture if the information the patient received was clear and easy to understand. During measure development, we convened a Patient Workgroup. The members of our Patient Workgroup stressed discharge instructions they received did not feel individualized and often much of the information was not applicable to them at all as an individual. While many patients are receiving discharge instructions, they are not always applicable to the patient and provide too little or too much information. We also recognize we did not conduct an initial pilot in ASCs, but we believe HOPDs and ASCs should not differ in their abilities to ensure that patients have all the information they need to properly recover once they are sent home.

Eight commenters referenced the OAS CAHPS. Commenters identified similarities between the Information Transfer PRO-PM and OAS CAHPS, posited the response rate for the OAS CAHPS may be affected if the Information Transfer PRO-PM was to be implemented alongside it, and suggested the OAS CAHPS could be used for implementation of the Information Transfer PRO-PM or concept measurement.

- One commenter suggested utilizing OAS CAHPS to implement this PRO-PM while another commenter noted that OAS CAHPS may already cover the measure construct. Two commenters suggested this PRO-PM may negatively affect response rates of OAS CAHPS. Three commenters suggested incorporating this PRO-PM's themes into the OAS CAHPS survey, which could minimize negative impacts on response rates of both surveys and minimize survey fatigue among patients. Another commenter suggested the similarity in cohorts would feel duplicative to patients and lead to a decrease in response rates for both.

Response: We appreciate the commenters' recognition that OAS CAHPS will be required in the ASCQR and HOQR programs, and the implementation of OAS CAHPS will require resources from ASCs and HOPDs. We will take this feedback under consideration for future measure implementation and acknowledge the following limitations of OAS CAHPS in addressing this measure gap: While individual facilities can add questions to the OAS CAHPS survey sent to patients, this would not be standardized and could not be reported as a quality measure unlike the Information Transfer PRO-PM we are developing. Additionally, the Information Transfer PRO-PM addresses multiple domains considered important to patients and not represented in OAS CAHPS. The domains addressed in the OAS CAHPS survey are not reported alone but as a sub-score combined with additional questions that are not applicable to the Information Transfer PRO-PM. Additionally, while there are similarities between OAS CAHPS and the Information Transfer-PRO-PM, there are also important differences between the two measure cohorts, mainly that this PRO-PM is designed to be sent to all patients receiving an outpatient procedure; in contrast, CAHPS only surveys a subset of major surgery patients.

Instrument

For reference, a copy of the survey instrument included in the call for public comment report is available in [Appendix B on pages 70-73](#).

Two comments supported the use of Patient-Reported Outcomes (PROs) if specific criteria could be met.

- One commenter suggested the Information Transfer PRO-PM be tested across a wide number of facilities to evaluate data collection burden, adequacy of survey questions to a range of health literacy, and can be improved through quality improvement activities. Another commenter was also concerned with potential data collection burden, usability of results, and survey fatigue.

Response: We appreciate the commenters' support for the use of PROs in healthcare quality measurement and plan to pilot the survey in a greater number of facilities prior to finalization of the measure. The outcome of the Information Transfer PRO-PM – patient understanding of information – is both relevant to clinicians and facilities and is an area where improvement activities can be conducted to raise measure scores. We developed the survey with extensive input from a national TEP, Patient Workgroup, and an initial pilot test at two HOPDs. The TEP and Patient Workgroup members helped word the questions clearly and succinctly and confirm they are understandable to a layperson as described in the methodology report we posted during the call for public comment. Additionally, during the initial survey pilot, physicians experienced no change in workflow or burden and were unaware the pilot was occurring. HOPD staff interviewed after the conclusion of the pilot also emphasized the survey administration process was burdenless. Finally, with respect to the concern about survey fatigue, we designed this survey to be as short and straightforward as possible to maximize participation.

Two commenters discussed the questions in the applicability (“Information was Applicable to Me”) domain questions.

- One commenter was concerned that the questions in this domain may be confusing to patients who might not fully grasp how certain information is applicable to them. Another commenter questioned what the title of the domain, “Information was Applicable to Me,” means.

Response: We thank the commenters for their insight into their understanding of the applicability domain. As development continues, we will investigate how to clarify the aim of these questions.

Three commenters discussed specific rewording, adding, or removing questions from the survey instrument.

- One commenter provided input on questions 3b and 3c. The commenter suggested rephrasing the first question to add recovery process and combining survey questions 3b and 3c or making the distinction between them clearer. Another commenter noted the phrasing “each day” in question 2b is not going to be applicable to all procedures/surgeries; they also shared that the word clear under Warning Signs or Symptoms may need a better definition. One commenter suggested language such as “Education was provided to me in my doctor’s office before the day of my surgery or procedure” indicates that some form of significant education beyond mere instruction was provided before the patient shows up on the premises where the procedure will take place and should be edited to better reflect best practice. One commenter suggested the respondent should be asked additional questions to elicit which features of this aspect of their care impacted their assessment of how clear various information was as well as eliminate the About You section.

Response: We appreciate all suggestions for the addition, subtraction, and adjustment of questions. Prior to the next pilot, CORE will evaluate all suggestions and make agreed upon changes. We will review these changes with our TEP and Patient Workgroup and incorporate their feedback on the revisions before finalizing the survey for the second pilot.

Five commenters supported a short survey and suggested survey fatigue would decrease survey responses.

- Two commenters noted the importance of keeping the survey as short as possible. One commenter noted that the addition of this survey could contribute to survey fatigue of patients. Another commenter emphasized that the domains addressed in the survey cover the spectrum of topics needed to collect essential details from the patient but cautioned that the possibility of survey fatigue remains and should be mitigated.

Response: We appreciate the commenters’ concern for patients experiencing survey fatigue. The survey was designed with patients in mind first and foremost and to be as fast and burdenless to complete as possible. Prior to the next pilot, highly correlated questions will be collapsed where possible to further shorten the survey.

Two commenters noted there is little variability in the measure results and stated concern over the number of facilities in the pilot.

- Both commenters expressed concern that there was not enough variation in performance identified by the measure to provide actionable data to patients and facilities. They requested a larger, more representative testing sample be used.

Response: We appreciate the commenters’ concerns about the lack of performance variation shown in the first pilot. This may be due to the small sample size as well as possible selection bias (HOPDs

already performing well in this area were most likely to agree to participate in the pilot). The next pilot, which will be larger than the initial pilot, will hopefully include more variation in the outcome to allow us to discriminate performance between facilities. However, we are aware that one of the challenges with PRO-PMs like ours is a “floor effect.” This occurs because patients generally like their healthcare providers and even poor performers are rated relatively well. Much of our work during the remainder of measure development will include options for modelling the outcome to allow for greater variation in performance, such as top box scoring or a composite measure.

One commenter suggested modifying the measure from a PRO-PM to a patient experience measure.

- This commenter noted the survey acts like a patient experience measure because it focuses more on processes, structural elements, and environment; whereas PRO-PMs traditionally focus on how the patients’ functional goals and overall goals of surgery were met.

Response: We thank this commenter for their suggestion. We agree that many important PRO-PMs focus on outcomes like functional status, pain, and cancer care. However, there are many other patient-centered care domains, like patient understanding, that are incorporated in PRO-PMs. The goal for patients undergoing elective outpatient surgery is to address some aspect of health that needs either screening or treatment. Patients’ ability to understand how to care for themselves after these procedures is essential to their recovery process and should be measured as a PRO-PM.

One commenter suggested the timing of the survey being sent be changed.

- This commenter noted that as the survey is distributed seven days following a surgery or procedure, it does not allow enough time to capture any longer-term effects from surgery.

Response: We thanked this commenter for the suggestion to increase the time after surgery that the survey is sent. We debated a longer measurement period during the initial stages of measure development. In conversations with our TEP and Patient Workgroup, we felt that 2-7 days was ideal for this measure because waiting longer could introduce recall bias in which patients do not remember what information they were provided. Furthermore, waiting longer to send the survey would likely result in lower response rates.

Risk Adjustment

Four commenters suggested adding additional risk- adjustment variables.

- One commenter suggested adding education level, pregnancy status, and race/ethnicity. Another commenter recommended surgery type, overall health, overall mental health, age, education, and how well the patient speaks English may affect survey results. Another commenter proposed risk stratification based on procedure type and the full range of social determinants of health should be included. Another commenter suggested the addition of census data may aid in the risk-adjustment model to address social determinants of health information that may not be readily captured. Additionally, one commenter suggested including malnutrition status and one commenter suggested examining response rates between patient populations.

Response: Several of the factors listed by commenters are already included in the survey, including patient education level, self-rated health, primary language, and race/ethnicity. Many of the other variables are either unrelated to the outcome or would be challenging to include in the survey. Nevertheless, we thank the commenters for their suggestions and will take them into consideration. Moreover, our measure testing has included comparing response rates, measure scores, and other

variables across different patient populations as part of validity testing. We will continue to conduct these analyses as part of measure development.

Measure Cohort

Two commenters provided recommendations on the measure cohort composition.

- Two commenters suggested keeping the measure cohort broad and inclusive of all types of surgeries and procedures, including non-surgical invasive procedures. Another commenter suggested the opposite, supporting any reduction in the overall number of patients surveyed to limit survey fatigue. They suggested only administering the survey to patients who are undergoing surgeries such as hip and knee replacements as this is a group of patients who have a longer recovery period. One commenter recommended retaining all major procedures, but then evaluating the minor procedures to determine if the procedure would be so minor that the survey is not appropriate. They also suggested identification of commonly performed procedures based on their global period (or major/minor distinction), which would contribute to a reasonable rate of return and help create targeted improvement cycles for these procedures.

Response: We appreciate the recommendations from all commenters and will take them into consideration when finalizing the measure cohort. Our intent is to maintain a broad measure cohort that includes a diverse set of procedures and surgeries since these patients should all receive clear and easy to understand information as part of their recovery process. However, as part of measure development and testing we may exclude certain procedures or surgeries that we deem as “minor” enough to not warrant inclusion in the measures.

One commenter suggested clarifying procedure type definition.

- This commenter requested the option “neither” be added in relation to procedure type.

Response: We thank this commenter for their recommendation and will look at defining this category.

Survey Implementation

There were eleven comments on the implementation strategy of the survey, four of which expressed concern of feasibility of implementation in ASCs, and one supported using a FHIR-based for implementation.

Five commenters addressed the concern of integration of digital measurement and implementation strategies, specifically in ASCs and with the suggested method of utilizing FHIR and APIs.

- These comments suggested that it is crucial to ensure smaller facilities and ASCs can integrate the selected implementation strategy into their systems, noting financial and administrative barriers. It was noted that only 50% of ASCs utilize EHRs and therefore digital quality measurement is not yet feasible within this proposed strategy, or in a short implementation timeline. Comments also highlighted the newness of FHIR standards, and as such, CMS should allow for greater adoption time in facilities, particularly for smaller or rural practices and EHR vendors. This would also considerably increase burden for ASCs, describing that there is currently no federal requirement for ASCs to implement an EHR.

Response: We appreciate the commenter’s feedback. CMS will consider this feedback during potential future implementation planning.

Two commenters specifically highlighted the potential data collection burden.

- The comments expressed concern over data collection burdens to the facility, clinician, practice, and patient. Furthermore, this adds an additional cost burden with no compelling evidence of need, and no clear responsibility of survey administration.

Response: We appreciate the commenter's feedback, noting that future implementation strategies will consider all additional burdens placed, ensuring the collected data will be used in a manner that reflects quality of the patient's understanding of the information they receive surrounding procedures and surgeries.

Three commenters included suggestions to optimize implementation strategies and improve response rates.

- Commenters suggested utilizing a third-party vendor for survey administration but exploring various modes of survey administration (phone, email, and/or text). Utilizing a mixed-mode approach and identifying options a patient will find least inconvenient or burdensome will increase their likelihood to respond to the survey. One commenter specifically supported email and text administration of the survey.

Response: We appreciate the commenters' feedback. We appreciate support for various modes of survey administration. Awareness of barriers to complete surveys can help improve participation rates in the patient population. Optimizing response rates is inherently tied to choosing a mode of survey administration that patients find the least burdensome and most user-friendly.

One commenter offered a suggestion to improve patient enrollment and data collection.

- The commenter suggested a process where patient enrollment is automatically initiated upon agreement of the surgery. The commenters also suggested adding the survey to the same platform of a third-party vendor that already exists and is used for appointment reminders and other notifications. They also suggested directing patients to websites to further gather information about their procedure or surgery, and relevant notifications. This commenter also suggested identifying ways to entice patients to engage with this survey, as it is relevant to their patient care experience.

Response: We appreciate the commenter's feedback and will consider this as part of future implementation possibilities.

Future Considerations

Four commenters discussed future considerations for implementation of the Information Transfer PRO-PM in the ASC setting.

- The commenters noted a lack of ASCs in the first (and planned for) the second pilot and believe testing in the ASC setting is necessary before CMS considers implementing the measure in the ASC setting. The commenters noted it would be important to better identify payer mix, caseloads, surgery type, and specialty representation. Furthermore, the commenters agreed with the planned pilot testing in many HOPDs and suggested this testing occur before ASC testing. They suggested this because it would allow for understanding how data may compare across ASCs and HOPDs. They anticipated measure scores would differ between the two settings given the inherent differences in the services provided, complexity of procedures and patients, and patient experience in ASCs versus HOPDs.

Response: We appreciate the commenters' feedback and support for the planned pilot testing. We agree with testing in the ASC setting to inform how the Information Transfer PRO-PM could be used to evaluate ASCs. Due to issues surrounding the feasibility of pilot testing the measure within the measure development timeframe, we were unable to include ASCs in the pilot testing phase of

measure development and focused on HOPDs for testing given the procedure mix in HOPDs. We believe the measure is best suited for HOPDs and may be considered for ASCs as well. We envision there will be opportunities to test the measure in ASCs, such as through pilot testing specific to the ASC setting or voluntary reporting for ASCs to allow for data collection before the measure would become mandatory.

One commenter questioned the use of the measure to assess outcomes for the facility and the patient.

- Specifically, the commenter considered how the measure will inform change in the practice, how the metrics will reflect performance, how the measure will detect change in clinical action over time, and how results will be reported to facilities.

Response: We appreciate the commenter's feedback and will consider these with further refinement of the instrument, when launching the second pilot, and preparing for later stages of implementation and measure use. However, the goal is for the measure to be implemented at the facility level, to provide patients with transparent data and aid them in selecting which facility to select for their procedure. On the facility side, the measure would provide facilities and their clinicians with data on how their patients rate the clarity of information they are provided and could help facilities target quality improvement initiatives.

One commenter also noted that reporting of data in a more user-friendly manner is favored, especially when reporting of OAS CAHPS becomes mandatory in CY 2024 for HOPDs and CY 2025 for ASCs.

- Specifically, the commenter noted OAS CAHPS data collected for HOPDs and ASCs participating in voluntary reporting is reported on the Provider Data Catalog. The commenter encouraged CMS report the OAS CAHPS data on the Care Compare website when OAS CAHPS becomes mandatory for HOPDs and ASCs.

Response: We appreciate the commenter's feedback and suggestions specific to OAS CAHPS. CMS will consider this advice for future data reporting.

One commenter encouraged replacement of an existing measure in the ASCQR program with the Information Transfer PRO-PM.

- The commenter suggested CMS replace the ASC-11 Measure (Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery) used in the ASCQR Program with the Information Transfer PRO-PM. The commenter suggested considering the Information Transfer PRO-PM for all relevant medical specialties as well as analyses of current practice patterns, gaps in care, and appropriate measure testing.

Response: We appreciate the commenter's feedback. CMS will take this into consideration for future assessment of measures within the ASCQR program.

Other

Two commenters expressed concern over continued development of this PRO-PM

- The commenters expressed concern over continuing with development of this measure, noting that robust testing in HOPDs and ASCs would be necessary to better understand real-world implementation. Certain points of concern also included feasibility of data collection, reliability and validity of the PRO and PRO-PM, and demonstrable variation in measure scores to justify the additional burden this measure may place.

Response: We appreciate the commenters' feedback and agree that robust measure testing is crucial to the development of a sound tool and measure to inform quality of care. Upon completion

of the second pilot, we will have more data that will allow us to formally test the issues raised by the commenter.

Preliminary Recommendations:

We plan to incorporate several of the recommendations received during public comment into the development and future implementation of our measure. Specifically:

- We will revise the language for several questions included in the survey instrument.
- We will conduct reliability and validity testing to address commenters concerns with response bias, variation in the measure outcome, adjusting for social risk factors, and survey modes.
- We will continue to examine implementation options for the survey and discuss these approaches with CMS to assist CMS in its efforts to determine the most viable path forward for the measure once it is completed.
- We will work with CMS to consider how to incorporate ASCs as part of a phased implementation approach to ensure that patients also have access to quality measurement data for these providers.

Overall Analysis of the Comments and Recommendations:

Commenters were generally supportive of the Information Transfer PRO-PM and agreed that patients should routinely have access to clear and easy to understand information about their recovery process for an outpatient surgery or procedure. Commenters offered many constructive suggestions to improve the instrument, risk-adjustment model, and measure specifications. The primary concerns among commenters centered around the notions of potential survey fatigue and implementation approaches.

We are encouraged that none of the comments expressed concerns with our survey development approach or the domains included in the measure. Comments related to modifications to the survey were minor and mostly related to wording changes. Other comments about measure testing will be addressed once we have more data as part of the second pilot and were already being considered as part of our analytic plans.

Commenters who expressed concerns referred to potential issues with measure implementation, survey fatigue, and overlap with OAS CAHPS. While OAS CAHPS does include some similar questions, the measure cohort, sampling approach, and survey timing all differ significantly from the Information Transfer PRO-PM. Moreover, OAS CAHPS does not address the Information Transfer PRO-PM measure since data on this outcome are not publicly reported. We agree that implementation is a vital component of this measure, and we will continue to evaluate different options for implementation not only with CMS but with our Patient Workgroup and TEP as well.

Appendix A: Verbatim Public Comments

Comment Number	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization	Text of Comments
1	April 6, 2022	Michael X. Repka, MD, MBA, American Academy of Ophthalmology	Medical Associations and societies	<p>The American Academy of Ophthalmology (the Academy) appreciates the opportunity to comment on the Yale New Haven Health Services Corporation - Center for Outcomes Research & Evaluation (Yale-CORE) methodology report on the development of a novel Patient-Reported Outcome-based Performance Measure (PRO-PM), titled “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure.” We support the development of the PRO-PM measure as having potential for a quality measure in the hospital outpatient department (HOPD) and ambulatory surgical center (ASC) settings. We recommend that CMS consider it as an alternative to ASC-11, a measure we feel strongly is not appropriate for the facility setting.</p> <p>The American Academy of Ophthalmology is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public.</p> <p>While the “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure” measure is being developed in HOPDs, expansion of the measure to the ASC setting may be considered in the future. Most ophthalmic surgical cases in the United States are performed in ASCs; therefore, we believe ophthalmologists are particularly well positioned to offer feedback, which is informed by our difficult experiences implementing the ASC-11 measure (Cataracts - Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery).</p> <p>The ASC-11 measure was developed for the Physician Quality Reporting System program; thus, it is not designed for use in the ASC facility setting. ASCs, which are neither licensed nor qualified to evaluate the cataract patient and make these required assessments, should not be involved in the professional decision-making intended by the measure. In addition to ASCs being an inappropriate body to evaluate cataract patients, any improvement in visual function would be attributable to the surgeon, not to the facility where the surgery occurred. In this way, there is a disconnect between the entity with control over the patient outcome and the entity being scored on the measure, thus making quality improvement near impossible. Furthermore, implementation of ASC-11 in the facility is extremely burdensome and resource-intensive for the reporting ASC as it requires the ASC to report on data that</p>

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				<p>is housed in the surgeon’s office and, thus, wholly inaccessible by the ASC. In fact, although governing regulations permit the surgical facility to exist adjacent to a physician’s office under certain circumstances, Medicare ASC Conditions for Coverage dictate that the two entities must be physically, administratively, and financially separate from one another. Ultimately, CMS decided to continue voluntary reporting for ASC-11 through the 2024 reporting year. While the Academy appreciates the flexibility, the flaws in the reporting methodology for ASC-11 are unresolved and we remain concerned because the measure will become mandatory for the 2025 reporting year. We would like to take this opportunity to again encourage CMS to consider removing the ASC-11 measure from the ASCQR program in future years.</p> <p>If developed for the ASC setting, the “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure” measure could replace the flawed ASC-11 measure. We would respectfully request that Yale-CORE and CMS carefully develop the PRO-PM with involvement of all relevant medical specialties, analyses of the current practice patterns, gaps in care, determination of factors that are within and not within the control of the physician/facility and potential consequences on the quality of patient care, testing of validity, reliability, and fairness, etc.</p>
2	April 7, 2022	Monica Wright, MHA, CPC, CPMA, CPCO, Society for Cardiovascular Angiography and Interventions	Medical Associations and societies	<p>The Society for Cardiovascular Angiography and Interventions (SCAI) appreciates the opportunity to comment on the Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure quality measure you currently have under development.</p> <p>SCAI is a non-profit professional association with over 4,500 members representing interventional cardiologists and cardiac catheterization teams in the United States. SCAI promotes excellence in interventional cardiovascular medicine through education, representation, and the advancement of quality standards to enhance patient care.</p> <p>Overall, SCAI agrees with the intent of the measure and appreciates the development of a patient reported outcomes measure that can be used in the outpatient hospital setting.</p> <p>Survey Instrument</p> <p>The measure description states that "The measure's goal is to capture patients' perceived understanding of the information provided to them about managing their recovery from the day they elected to undergo the surgery or procedure through the</p>

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				<p>day they respond to the survey."</p> <p>Elective procedures may be scheduled many months in advance. While we appreciate asking the patient to take into account all materials they received in regard to their recovery, we have concerns that items discussed that long ago will be forgotten. For measurement purposes, it may be better to limit the survey to information received at the facility, within more recent memory.</p> <p>The section of the survey entitled Information was Applicable to Me appears a bit confusing. How the questions are applicable may not be easily understood by patients. For example, patients may not connect how patient instructions apply to their insurance coverage without an example such as your medications were on your insurance's formulary.</p>
3	April 8, 2022	Lisa Satterfield, MS, MPH, CAE, CPH, The American College of Obstetricians and Gynecologists	Medical Associations and societies	<p>The American College of Obstetricians and Gynecologists (ACOG) represents more than 62,000 physicians and partners dedicated to advancing women's health and the health of individuals seeking obstetric and gynecologic care. We are engaged on a number of topics regarding Medicaid, Medicare, and private payer issues, including quality measure maintenance and development. ACOG appreciates the opportunity to provide feedback on the new Centers for Medicare and Medicaid Services (CMS) and Yale New Haven Health Services Corporation - Center for Outcomes Research and Evaluation (CORE) development of a new patient-reported outcome-based performance measure (PRO-PM) titled <i>Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure</i>. Please see our detailed feedback below.</p> <p><i>General Feedback</i></p> <p>Obstetrician-gynecologists perform a plethora of outpatient procedures including hysterectomy, fibroid ablations, myomectomy, and salpingectomy. As such, ACOG is encouraged by the development of patient-centered measures for outpatient surgeries and procedures. Overall, this measure has the potential to be effective in informing providers and practices of their impact in communicating key information related to the outpatient surgery/procedure recovery process with the intention of improving their patient's understanding. Additionally, engaging patients in the improvement of their health care experience is key to creating more patient-focused processes.</p> <p><i>Survey Instrument</i></p> <p>The public comment is requesting comment on the design of the survey instrument, specifically around streamlining/clarifying the introduction, removing, or adding</p>

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				<p>questions, and ways to increase the response rate. In general, the survey is easily understandable to a lay audience. Below are suggestions regarding the survey instrument:</p> <ul style="list-style-type: none"> • Regarding the sentence before Question 1, consider adding “recovery process” to the sentence to clarify that focus of the inquiry and measure. For example, “When answering the survey questions please think about all of the information you were given about your surgery/procedure recovery process, from the day you decided to get your surgery/procedure until now.” • Questions 3b and 3c encompass important components to consider in tailoring a patient’s recovery process information. However, a patient completing this survey may see little distinction between the two questions. Either combining the questions or being clearer in the distinction (i.e., personal and home situation vs community environment) could be useful in improving the patient’s understanding of the survey questions and potentially reduce instances of missed questions. <p>Risk Adjustment</p> <p>The public comment is seeking suggestions for additional risk variables that should be considered for inclusion. Important variables for risk adjustment are already being included such as age, sex, primary language, insurance type, surgery type, and missingness of questions. CORE should consider adding education level and race/ethnicity as points of risk adjustment since they will already be collected as part of the survey process. These two points are important pieces to the health equity and disparities picture that will benefit from risk adjustment practices. Additionally, it should be considered to add pregnancy status as a datapoint collected as part of the survey process and also included as a point of risk adjustment for the measure.</p> <p>Measure Cohort</p> <p>The public comment is considering whether to refine the measure cohort by limiting the cohort to only include patients undergoing a procedure or surgery classified as major or minor by CMS’s definitions and patients undergoing non-surgical invasive procedures (i.e., colonoscopy, endoscopy, cystoscopy). Below are suggestions for the measure cohort.</p> <ul style="list-style-type: none"> • Keep the measure cohort broad and inclusive of all types of surgeries and procedures, including non-surgical invasive procedures. When adding layers to restrict cohorts, it is possible to run across errors in the vendor’s eligible patient identification system and those who would otherwise be eligible to complete the survey may fall through the cracks.

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				<ul style="list-style-type: none"> • When reviewing the survey characteristics, it would be helpful for CORE to clarify what “Neither” means in regard to surgery type. <p>Survey Implementation</p> <p>The public comment is seeking suggestions on survey implementation and how to implement the survey in a way that places minimal burden on hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), providers, and patients. Overall, it would be helpful to have more clarity on the logistical timeline between the patient’s surgery/procedure date and completion of the survey. Understanding this flow is incredibly helpful to identify areas that can benefit from improvement in survey implementation prior to being fully launched. Below are suggestions for survey implementation.</p> <ul style="list-style-type: none"> • When considering potential hurdles in survey implementation, it is important to ensure that smaller facilities and ASCs can manage integrating the system into their existing processes. Barriers, including financial and administrative, could result in minimal uptake of this measure by less-resourced facilities and ASCs. • It is also important to take into consideration that many surgery programs have lag periods between the uploading of data on patients, identification of eligible patients, sending out of links to complete the survey, completion of the survey, and receipt of survey results. These lags can be detrimental in receiving the most accurate patient reported information and lead to less reliable measure data. <p>Future Considerations</p> <p>The public comment is seeking general comments on expanding the second pilot to include ASCs. Doing this will be beneficial to evaluating the performance of the measure in different settings. CORE should also consider other factors in determining pilot HOPDs and ASCs to include such as payer mix, caseload, types of surgeries performed, and specialty representation.</p>
4	April 8, 2022	Fareen Pourhamidi, MS, MPH, American College of Cardiology		<ul style="list-style-type: none"> • It would be beneficial to ensure that the survey is authored in a manner consistent with health literacy standards. • As FHIR standards are relatively new to the marketplace, allowance of more time for adoption of these standards should be afforded to smaller EMR vendors. • Greater clarity is needed regarding mechanisms for ensuring follow-up and as to which stakeholder (e.g., the facility or the provider) has the responsibility for this activity. • The intended context of use is slightly unclear. How will the results be used in

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				<p>outcomes assessment for both the facility and the patient? How will it inform the change in practice?</p> <ul style="list-style-type: none"> • What metrics will be used to reflect performance (e.g., proportion of patients achieving a specific score change)? <ul style="list-style-type: none"> o How will the measure detect changes in clinical action? (How to detect changes over time?) o What, if any, are the related quality measures? o How will results be reported to facilities? • More detail regarding mechanisms of attribution would be of benefit. Facility-oriented or provider-oriented? If provider-oriented, will attribution occur at the subgroup or department level? How will work performed by Advanced Practice Providers be attributed? This is relevant in that with PECOS such providers are classified as “primary care” providers even if their place of practice is within a specialty practice.
5	April 10, 2022	Kathy Wilson, RN, MHA, ASC Quality Collaboration (ASC OQ)		<p>Please accept the following comments from the ASC Quality Collaboration (ASC QC) regarding the development of a novel Patient-Reported Outcome-based Performance Measure (PRO-PM) pertaining to Key Information Related to Recovery From an Outpatient Surgery or Procedure. The ASC QC is a non-profit organization dedicated to advancing quality measurement and public reporting in ambulatory surgery centers (ASCs) through a collaborative effort of ASC stakeholders. These stakeholders include leaders from ASC management companies, industry associations, professional physician and nursing associations, accreditation organizations and information technology companies. Collectively, these organizations represent over 1,700 ASCs. We appreciate the opportunity to provide input into any measures that will potentially affect our member organizations and their ASCs.</p> <p>While your background information provides several cited references, we question the statement that "HOPDs and ASCs fail to provide patients with critical information about recovery at a much higher rate than inpatient hospitals." ASCs have regulatory and accreditation requirements which address the preparation for discharge and recovery at home. Not only are written instructions provided to the patient and caregiver, but postoperative phone calls are made to help clarify any information that is provided. The information provided by ASCs may actually be more concise and patient centered because it is tailored to each patient’s needs</p>

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				<p>rather than being a standard set of instructions generated by a computer program.</p> <p>Also of note is the fact that ASCs and HOPDs are in the process of implementing the OAS CAHPS survey. We see this as an important quality measure that is applicable to both of these outpatient settings, and we support it becoming a mandatory measure in the ASC Quality Reporting Program. This implementation will require resources on the part of the ASCs and will be burdensome financially to many. It is not advisable to add another measure which may require external vendor administration and associated cost. It is acknowledged that it does not meet the same criteria for patient reported outcomes, but the timing could potentially place additional resource burden on ASCs. There are questions related to Recovery and Discharge Instructions included in the OAS CAHPS survey. If more specific questions are indicated, then would it be possible to add those to OAS CAHPS? It seems it would be far less costly and less duplicative to explore that.</p> <p>In response to your specific areas for which feedback is sought:</p> <ol style="list-style-type: none"> 1. Survey Instrument: We support any effort to shorten the survey and therefore lessen the degree to which patients may feel survey fatigue, especially in light of the OAS CAHPS implementation timeline. Specific comments regarding the survey itself: <ol style="list-style-type: none"> a. The questions do not seem to address the fact that some of the information related to preparation for surgery, recovery and discharge are imparted by the surgeon's office. b. Under General Information, question 2b- "each day" is not going to be applicable to all procedures/surgeries. In addition, this can vary greatly from patient to patient. Is this General Information section based on all sources of information, or just information obtained from the facility? c. Header Information was Applicable to Me-what does that mean? That the information was specific enough? d. Under Warning Signs or Symptoms, what does the word CLEAR mean here? Perhaps that needs better definition. 2. Risk Adjustment: We do not have any comments related to additional risk variables. Please see note below regarding specific procedures to consider. These

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				<p>may have their own risk variables.</p> <p>3. Measure Cohort: With regards to the target population, we would support any reduction in the overall number of patients surveyed in order to limit the survey fatigue mentioned above. Perhaps this could be administered to patients who are undergoing surgeries such as hip and knee replacements since this is a group of patients who have a longer recovery period. These procedures are also particularly important as the volume shifts from inpatient to outpatient.</p> <p>4. Survey Implementation: We support email and text administration of a survey. In fact, we encouraged CMS to adopt an email mode for OAS CAHPS. However, the 2019 mode experiment showed a lower response rate with straight email than email with phone or mail follow up. It is interesting that it is being considered here, and we encourage any mode of administration that is less costly to the ASCs.</p> <p>It should also be noted that there is at most a 50% adoption of Electronic Health Records in ASCs. We agree moving toward digital quality measurement is desirable, but do not believe this is practical in the ASC setting over the very short implementation time frame CMS envisions. ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 establishing an incentive and penalty program to encourage adoption of EHRs, and past environmental scans have shown the use of EHRs in the ASC industry to be more limited than in other healthcare settings. Further, the ASCQR Program does not currently include any electronic clinical quality measures (eCQMs).</p> <p>5. Future Considerations: Regarding future implementation in the ASCs, we encourage any measures that provide comparable data across ASCs and HOPDs. We would like to see additional pilot testing in a large number of HOPDs as planned before consideration would be given to testing this for ASC implementation.</p>
6	April 11, 2022	Dyane E. Tower, DPM, MPH, MS, American Podiatric Medical Association		<p>On behalf of the American Podiatric Medical Association (APMA), the premier professional organization representing the vast majority of the nation’s doctors of podiatric medicine (DPMs), also known as podiatrists or podiatric physicians and surgeons, we appreciate the opportunity to share information regarding the proposed “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure” Patient-Reported Outcome-based Performance</p>

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				<p>Measure (PRO-PM). Many podiatric surgical procedures are performed in hospital outpatient departments (HOPD) and ambulatory surgery center (ASC) settings. And, as mentioned in the Methodology Report, the frequency and complexity of outpatient operations performed in these settings is increasing as we learn more about cost and access to care. Podiatric physicians and surgeons are dedicated to providing patients with safe and effective healthcare, thus APMA supports the development of a patient-reported outcome-based performance measure related to patient’s level of understanding of post-procedure care.</p> <p><u>Survey Instrument</u> Regarding the survey instrument, APMA supports the survey being:</p> <ul style="list-style-type: none"> • managed by a third-party vendor; • sent to the patient via text or email as it appears that is preferred by the patient; • inclusive of all information provided and not limiting to just “discharge instructions;” and • of a short length to limit survey fatigue. <p>In regard to the last bullet, APMA recommends that YNHSC consider narrowing the survey down further if the interitem correlations allow for identifying questions that are repetitive.</p> <p><u>Survey Implementation</u> Regarding survey implementation, APMA appreciates that effort is being made to minimize as much of the potential burden on providers and patients when designing and implementing this measure. However, we recommend the following:</p> <ul style="list-style-type: none"> • Consideration could be given to a process where a patient’s enrollment could be automatically initiated when the patient agrees to the surgery/completes the pre-operative paperwork in the provider’s office. Many outpatient offices already use a third-party service to send appointment reminders, etc. and maybe the survey could be added to any one of those already utilized platforms. An alternative could also be that the patient could be directed to the provider’s website to learn more information about their upcoming surgery and provide a link for patients to sign-up to be kept up to date on post-op appointments, additional post-op care, etc. • The “enrollment” into this survey should seem enticing and an important part of

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				<p>the patient’s care experience, such as to make sure they understand the appropriate steps they will need to take to improve their recovery and/or that crucial information is shared with them for their recovery.</p>
7	April 11, 2022	Koryn Rubin, American Medical Association	Medical Associations and Societies	<p>The American Medical Association (AMA) appreciates the opportunity to comment on the methodology report on the Patient Understanding of Key Information Related to Recovery From an Outpatient Surgery or Procedure. The AMA supports the assessment of patient-reported outcomes (PROs) but believes that:</p> <ul style="list-style-type: none"> • This patient-reported outcome performance measure (PRO-PM) should be tested across a wide number of facilities; • The burden of data collection to the clinician, facility, and patient must be adequately evaluated; • The PRO survey must demonstrate that it assesses outcomes that are relevant to the clinicians and facilities being measured and authored in a manner consistent with health literacy standards; and • The PRO-PM results demonstrate meaningful gaps in care on which quality improvement activities can be focused. <p>The Centers for Medicare and Medicaid Services (CMS) must ensure that the measure is tested across a diverse set of facilities and include ambulatory surgical centers (ASCs) as well as Hospital Outpatient Departments (HOPDs). As a part of this testing, the AMA strongly urges CMS to assess the feasibility and potential data collection burden to the facility, clinician, practice, and patient as we do not believe that these concerns have been adequately evaluated in previous PRO-PMs developed by CMS. Specifically, it is important to evaluate how the testing sites coordinate data collection across settings or on whom the responsibility of the survey was placed. These questions are particularly important since it is imperative that CMS and others minimize the duplication of effort in collecting these data required for the measure as well as the potential risk adjustment variables. While Fast Healthcare Interoperability Resources (FHIR) may be useful to collect and report the data, the standards are still relatively new and CMS must allow more time for their adoption, particularly for smaller or rural practices and electronic health record vendors.</p> <p>The AMA also believes that it is critical to thoroughly evaluate the timing and number of items solicited throughout the data collection process to ensure that the PRO implementation does not result in survey fatigue. For example, does the collection of this survey lead patients to be less likely to complete other surveys such</p>

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				<p>as HCAHPS or CG-CAHPS? Are these questions better suited to be included as supplemental items on an existing survey to reduce data collection burden? We believe that it is critical to understand the potential impact and burden that could be experienced from the patient’s perspective. While the data collection process and burden may seem reasonable for one measure, what is the potential long-term impact on patients, facilities, clinicians, and practices as more and more PRO-PMs are implemented?</p> <p>In addition, the PRO-PM must be linked to other quality measures and be able to detect changes in clinical action. The AMA is concerned that this PRO-PM will not demonstrate sufficient variability to enable patients, caregivers, and others to make informed decisions regarding the quality of information provided to patients during the recovery process, particularly in the HOPD and ASC settings. Our concerns relate to the study referenced in the comment documents, which compared documentation practices across inpatient and ambulatory settings (Downey, 2021) and the average score by survey question in Figure 3. Regarding the study, we note that only four surgery center units were included, which we do not believe is representative of the setting(s) of interest in this PRO-PM. In addition, Figure 3 shows that the average scores ranged from 2.62 to 2.84, which implies minimal variation across the pilot sites. As a result, it remains unclear how the results could be aggregated to distinguish the quality of care provided by an HOPD or ASC and we question whether this initial testing demonstrates sufficient variability to justify continued development of this PRO-PM.</p> <p>The AMA urges CMS to consider whether this PRO-PM should continue to be developed and if development continues, we urge CMS to conduct robust testing. This testing should assess the feasibility of data collection of the PRO and other data elements required for risk adjustment, the reliability and validity of the PRO survey, and the reliability and validity of the PRO-PM across a wide range of facilities and patients.</p> <p>Reference: Downey E, Olds DM. Comparison of Documentation on Inpatient Discharge and Ambulatory End-of-Visit Summaries. <i>J Healthc Qual.</i> 2021;43(3):e43-e52.</p>
8	April 11, 2022	Samir A. Shah, MD, FACG; John M. Inadomi, MD, AGAF; Douglas K. Rex, MD, MASGE,	Medical Associations and Societies	On behalf of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and American Society for Gastrointestinal Endoscopy (ASGE), we wish to thank you for the opportunity to comment as the

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		American College of Gastroenterological Association (AGA) and American Society for Gastrointestinal Endoscopy (ASGE)		<p>Center for Medicare & Medicaid Services (CMS) develops a patient reported outcome-based performance measure (PRO-PM), titled Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure. Our societies strongly agree with CMS that the development of PRO-PMs should be a high priority. The manner in which they are developed is critical to gaining their acceptance by patients, clinicians, and facilities. Our specific comments on this measure are as follows.</p> <p>Importance to Measure While we find the measure has a clear focus, our societies do not fully agree with the premise. The methodology report states that “HOPDs [hospital outpatient departments] and ASCs ambulatory surgery centers] fail to provide patients with critical information about recovery at a much higher rate than inpatient hospitals.” The GIQuIC clinical data registry, a joint collaboration of the ACG and ASGE, collects data on colonoscopy and esophagogastroduodenoscopy (EGD) procedures from over 4,700 physicians (one-third of US practicing gastroenterologists) at over 730 GI endoscopy units. The registry currently has data on over 14 million colonoscopy cases and 3 million EGD cases. Participating units span settings from ASCs (~80%), hospitals (~15%), and offices (~3%). One mandatory question associated with each case submitted to the registry is “Were written discharge instructions provided to the patient?” Yes responses must then answer specific questions about the discharge instructions (i.e., diet, return to activities, potential adverse events, emergency contact number, and medication resumption). Study level performance demonstrates >93% performance on this measure for each year from 2019-2021. 2 Further, the vast majority of ASCs undergo surveys by recognized accreditation entities, such as the Accreditation Association for Ambulatory Health Care and The Joint Commission, which have medication reconciliation standards. The lack of a gap in care on this measure appears to be further borne out by the results of the initial pilot study.</p> <p>Informed Patient Decision-Making We are concerned that this PRO-PM will not demonstrate sufficient variability to enable patients, caregivers, and others to make informed decisions regarding the quality of information provided to patients during the recovery process, particularly in the HOPD and ASC settings. Our concerns relate to the study referenced in the</p>

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				<p>comment documents, which compared documentation practices across inpatient and ambulatory settings (Downey, 2021) and the average survey score by survey question in Figure 3. Regarding the study, we note that only four surgery center units were included, which we do not believe is representative of the setting(s) of interest in this PRO-PM. In addition, Figure 3 shows that the average scores ranged from 2.62 to 2.84, which appears to imply minimal variation across the pilot sites. As a result, it remains unclear how the results could be aggregated to distinguish the quality of care provided by an HOPD or ASC and we question whether this initial testing demonstrates sufficient variability to justify continued development of this PRO-PM.</p> <p>Survey Implementation We strongly encourage CMS to assess the feasibility and potential data collection burden to the facility, clinician, practice, and patient as we do not believe that these concerns have been adequately evaluated in previous PRO-PMs developed by CMS. Specifically, it is important to evaluate how the testing sites coordinated data collection across settings or on whom the responsibility of the survey was placed. This question is particularly important since it is imperative that CMS and others minimize the duplication of effort in collecting these data required for the measure as well as the potential risk adjustment variables.</p> <p>We also believe that it is critical to thoroughly evaluate that the timing and number of items solicited throughout the data collection process were appropriate and do not result in survey fatigue. For example, does the collection of this survey lead patients to be less likely to complete other surveys such as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS), or Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS)? Are these questions better suited to be included as supplemental items on an existing survey to reduce data collection burden? We believe that it is critical to understand the potential impact and burden that could be experienced from the patient’s perspective. While the data collection process and burden may seem reasonable for one measure, what is the potential long-term impact on patients, facilities, clinicians, and practices as more and more PRO-PMs are implemented?</p>

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				<p>CMS must assess the potential long-term impact on patients, clinicians, and facilities as more and more PRO-PMs are implemented.</p> <p>Considerations for the ASC Setting We appreciate the opportunity to comment on issues to consider when expanding the measure to the ASC setting. Our societies are concerned about the lack of representation of ASCs in the pilot studies knowing this measure could be used for both the HOPD and ASC. 3 First, it should be recognized that the patient experience will be different based on care setting. While the HOPD and ASC settings share similarities, such as the human resources and equipment required for endoscopic procedures, the patient mix is generally different. The HOPD tends to be the preferred site of service for patients undergoing urgent procedures and complex procedures or those patients with greater comorbidities undergoing elective procedures. As such, the HOPD may offer services such as emergency and intensive care not typically available at ASCs. Such differences may result in very different experiences and by extension measure scores, especially if the survey tool is designed with the HOPD as the care setting.</p> <p>Further, recognizing that ASCs are more cost-efficient care settings, costs associated with staff time and a third-party vendor to implement this measure could be unduly burdensome, restricting access to care in the ASC setting. Facility staff will be required to upload data on a weekly basis for survey distribution, potentially using new, unfamiliar technologies (e.g., Fast Healthcare Interoperability Resources, Application Programming Interfaces). Staff may also need to address questions from patients who receive this survey as well as the similar OAS CAHPS survey. A clearer understanding of costs related to staff time and the third-party vendor is essential.</p> <p>Our societies strongly believe further consideration should be given to deploying this measure for the ASC setting only if the measure is piloted with representation from ASCs to gather an understanding of real-world implementation and the results demonstrate sufficient variability to justify the resource burdens.</p> <p>If you have any questions about our comments or if we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org, Leslie Narramore, AGA, at 410-349- 7455 or</p>

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9	April 11, 2022	William Prentice, CEO, Ambulatory Surgery Center Association		<p data-bbox="1060 269 1793 329">Lnarramore@gastro.org, or Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.</p> <p data-bbox="1060 337 1982 654">The ASC community coalesced behind a group of stakeholders 15 years ago to develop, test, and seek endorsement of measures specific to the ASC setting through the ASC Quality Collaboration (ASC QC). We proactively requested our own quality reporting program, the ASC Quality Reporting (ASCQR) Program, and our facilities have been submitting data to the Centers for Medicare & Medicaid Services (CMS) since 2012. ASCA strongly supports quality reporting measures that speak to the quality of care being provided by the facility and that will help improve care as well as the patient experience. We have serious concerns, however, that this survey lacks sufficient clinical support and that the burden will far outweigh any perceived benefits.</p> <p data-bbox="1060 695 1192 719">Importance</p> <p data-bbox="1060 727 1976 979">The Methodology Report indicates that hospital outpatient departments (HOPDs) and “ASCs fail to provide patients with critical information about recovery at a much higher rate than inpatient hospitals.” It is extremely misleading to include ASCs in this statement, when the Methodology Report provides absolutely no research indicating this is a problem in the ASC setting. One study was cited, based on a review of 233 patient visits in 20 hospitals. It is presumptive to apply this study to ASCs when only hospitals (inpatient and ambulatory units, also known as HOPDs) were evaluated.</p> <p data-bbox="1060 987 1961 1044">In fact, when it comes to post-operative outcomes, which the Methodology Report uses as a rationale for the survey, ASCs routinely fare better than hospitals.</p> <p data-bbox="1060 1052 1976 1141">According to a National Institutes of Health (NIH) study,¹ ASCs fared significantly better than hospitals, particularly when comparing 30- and 90-day readmission rates and post-surgical complications for inpatient and outpatient procedures.</p> <p data-bbox="1060 1149 1115 1174">Pilot</p> <p data-bbox="1060 1182 1965 1369">While it is the stated intent of the measure developers that this measure will apply to ASCs, there is no indication the survey will be tested in our site of service. The first pilot included only two HOPDs and no ASCs. The Methodology Report indicates the second pilot will include “at least 15 HOPDs.” The survey should not be recommended for use in the ASC setting until it is adequately tested in the ASC setting.</p> <p data-bbox="1060 1377 1325 1401">Survey Implementation</p>

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				<p><u>Cost Burden for Facilities</u> Just as with the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS), which becomes mandatory for ASCs in 2025, this new PRO-PM would require the ASC to use a third-party vendor. This adds cost to our facilities, which already receive much lower reimbursements on average than HOPDs for performing the same procedures. Sharp increases in labor costs and other overhead are impacting all in healthcare, and Medicare rates consistently fail to keep up with inflation. Adding an additional cost burden with no compelling evidence of the need is unwarranted.</p> <p><u>Lack of EHR Technology in the ASC Setting</u> The Methodology Report references Fast Healthcare Interoperability Resources (FHIR) and indicates that “CMS may be able to lower provider implementation burden through specifying the data elements for the measure in the FHIR standard.” Unfortunately, many ASCs are simply not equipped with electronic health record (EHR) technology. While the Office of the National Coordinator of Health Information Technology (ONC) estimates that at least 86 percent of office-based physicians and 96 percent of acute care hospitals are currently using an EHR, we estimate that at most 50 percent of ASCs are using an EHR.</p> <p>Additionally, many of those ASCs with EHRs are likely using inpatient products that are ill-fitted to the operational needs of an ASC. ASCs did not receive any federal funding for EHR adoption in the HITECH Act of 2009 and should not be penalized for slower adoption of health information technology (health IT). Both Congress and CMS have recognized the lack of EHR availability in ASCs. There is no federal requirement for ASCs to implement an EHR, and ASC-based clinicians (those clinicians who furnish 75 percent or more of their covered services in an ASC) are exempt from the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS). While ASCs are subject to the policies finalized in the ONC’s 21st Century Cures Act Final Rule, it should be noted that that rule contains several exceptions for sites of service with limited access to electronically stored health information. For example, ASCs are not responsible under Information Blocking for any health information not stored in electronic format.</p> <p>Given the current lack of health IT in ASCs, it is likely that a transition to FHIR-based quality reporting would provide a considerable burden for many of the 6,100 Medicare-certified ASCs. It would also provide an inaccurate picture of quality in</p>

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				<p>ASCs as compared to offices and hospitals who have had years to integrate health IT components into their clinical and administrative processes.</p> <p>Survey length</p> <p>In the “Summary of Technical Expert (TEP) Meeting April 23, 2021- Patient Receipt of Key Information Following Outpatient Procedure Patient-Reported Outcome-Based Performance Measure (PRO-PM)” document, it was discussed that all patients in the seven-member patient workgroup agreed they are experiencing survey fatigue in all facets of their lives. This survey would only contribute to that fatigue and potentially cannibalize other CMS-mandated surveys such as OAS CAHPS. While the Methodology Report indicates the survey is only 12 questions long, several of the questions have multiple parts, which makes the survey 22 questions long. OAS CAHPS is 34 questions long. In addition to this survey’s potential to create additional burden and confusion for patients, measure developers should consider anything that will negatively impact already-low return rates.</p> <p>ASCA strongly supports quality reporting measures that ensure our facilities are providing the highest quality of care to our patients. We have serious concerns, however, that this measure is addressing a problem that has not been demonstrated to exist in the ASC setting and will present an undue cost burden on our facilities. Please contact Kara Newbury at knewbury@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.</p>
10	April 11, 2022	Kaycee M. Glavich, Press Ganey		<p>We thank the Center for Outcomes Research & Evaluation (CORE) and the Centers for Medicare & Medicaid Services (“CMS”) for the opportunity to comment on the Development of a Measure of “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure.” Press Ganey is the leading provider of patient experience measurement, performance analytics and strategic advisory solutions for health care organizations across the continuum of care. For more than 30 years, our mission has been to help health care organizations reduce patient suffering and improve clinical quality, safety, workforce and caregiver engagement, and the patient experience. As of January 1, 2022, we served more than 41,000 health care facilities, including partnering with over 75% of all acute care hospitals and thousands of ASCs. While we generally support CMS and CORE’s efforts to assess patient understanding and increase the quality and amount of information that is provided to patients after a procedure in a hospital-based outpatient department (HOPD) or ambulatory surgical center (ASC), we are concerned this measure is duplicative of the Outpatient and Ambulatory Surgical</p>

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				<p>Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey in content, patient cohort, and administration. To alleviate patient confusion and provider burden, we urge CMS to incorporate this measure concept into the OAS CAHPS survey.</p> <p>SURVEY CONTENT The patient-reported outcome performance measure (PRO-PM) in development is duplicative of content from the OAS CAHPS survey. If CORE and CMS believe there are items from the CORE PRO-PM that are not currently covered by the OAS CAHPS survey, we urge CORE and CMS to incorporate these themes into the OAS CAHPS survey, as opposed to administering the survey separately. CMS recently finalized inclusion of the OAS CAHPS survey as a mandatory measure within the Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs in 2024 and 2025, respectively. Thus, the OAS CAHPS survey has national recognition as a standardized measure of patient experience and will soon be recognized as the primary source of patient experience data for the outpatient and ASC settings. CORE notes that the aim of this PRO-PM is to assess patients' perceived understanding of key information related to their recovery process after undergoing an outpatient procedure or surgery. However, the OAS CAHPS survey already includes questions about discharge information, expectations during recovery, and provider-patient communication about side effects of the procedure. Moreover, the OAS CAHPS survey is a standard, validated, and reliable measure of patient experience for adult patients who visited Medicare-certified HOPDs or ASCs for a surgery or procedure. The CORE also noted that many patients from their patient workgroup reported that they "preferred yes/no response options" to survey questions. The OAS CAHPS survey includes several yes/no response options, mostly within the Preparations for Discharge and Recovery domain, which generally covers the topics that the PRO-PM aims to address. OAS CAHPS questions that do not have a yes/no response option are generally Yes, Definitely/Yes, Somewhat/No. We also have comments as it relates to some of the individual survey items. Specifically:</p> <ul style="list-style-type: none"> • Questions (Q) 1 through 3 are currently in a declarative format, or a statement. This differs from the rest of the questions on the survey which are in an interrogative format, or a question. We urge CORE and CMS to revise those items to an interrogative format, such as Which sources of information did you use for your recovery? (Please select), or did the information you get about recovery help you...? • It is also unclear how the respondent should proceed on the survey if they select

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				<p>“None of the above” in response to Q1. If the respondent reports that they received no information from the sources listed then they will be unable to answer the remaining questions, but there is no “skip to” instruction provided.</p> <ul style="list-style-type: none"> • On Q4a-c, instead of a “Does not apply” response option, we urge CORE and CMS to include a screener question, such as Were you told to take any medications as part of your recovery? This will reduce respondent burden. • Lastly, we urge CORE and CMS to reevaluate Q4a, Q4b, Q5a, and Q5b. These questions are double-barreled and could confuse the respondent or lead them to provide an answer that is not satisfactory or even inaccurate. For example, on Q5b, the respondent might be unable to appropriately answer the question if they were given clear information about whom to contact about unexpected symptoms but not how. <p>MEASURE COHORT AND RISK ADJUSTMENT Patients are considered eligible for the OAS CAHPS survey if they visited a Medicare-certified HOPD or ASC for a surgery or procedure, regardless of payer, and meet all other eligibility criteria. This is very similar to the criteria outlined by CORE for the PRO-PM, so both instruments (if administered separately) would largely target the same patient population and could appear duplicative and burdensome to patients who receive both surveys, likely having a negative impact on response rates for both surveys. CMS and their subcontractor have already performed two mode experiments and field tests to assess (1) the validity and reliability of the OAS CAHPS survey, (2) the effects of using different data collection modes of administration, and (3) whether ratings of care within an HOPD or ASC varied by patient characteristics. 1 During the most recent mode experiment, which occurred in 2019, CMS determined that there were no significant differences in results based on survey mode but there were differences in responses attributable to patient characteristics, including surgery type, overall health, overall mental health, age, education, and how well the patient speaks English. If the PRO-PM items are incorporated into OAS CAHPS, we would not expect to see a negative impact on OAS CAHPS response rates and a separate risk adjustment may not be needed.</p> <p>SURVEY IMPLEMENTATION, MODES, AND RESPONSE RATES Given that the OAS CAHPS survey already allows multiple modes of administration, including web-based options which garner demonstrable higher response rates, incorporating the PRO-PM themes into the OAS CAHPS survey could increase the data collected for the PRO-PM measures and not negatively impact response rates for both surveys. CORE</p>

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				<p>notes that the PRO-PM survey was administered by a third-party vendor via text/email to patients. Currently, CMS allows the OAS CAHPS survey to be administered by a third-party vendor via mail only, phone only, mail followed by phone, web (email) followed by mail, and web (email) followed by phone. While we continue to encourage CMS to include both email and text invitations to web-based surveys, it is important that these modes are used as part of a mixed mode approach to allow the HOPD/ASC to choose the mode that is most appropriate for their patient population and allow patients to respond using their preferred mode, providing the opportunity to maximize response rates. Only providing a text/email option for the PRO-PM could inadvertently exclude many patients from participating in the survey, including those that are not technologically savvy, are visually impaired, or lack access to the internet. Further, while the methodology document indicated patients consented to receiving a survey as part of their intake forms, there was no discussion on how CMS intends to ensure that the text option meets requirements of the Telephone Consumer Protection Act (TCPA) regarding prior consent and any relevant state laws or regulations on initiating phone calls or text messages. Additionally, CORE noted that feedback from the patient workgroup included that “everyone agreed they are experiencing survey fatigue.” Administering a separate survey to patients would increase the already-fatigued group of patients, which would likely decrease response rates for both OAS CAHPS and the PRO-PM. Moreover, the response rates published by CORE (page 9 of the Methodology Report) are lower than the overall response rates for most of the administration modes for OAS CAHPS, including the new web-based modes that CMS has approved (39% for webmail and 35% for web-phone). This PRO-PM is also not the only PRO measure currently being evaluated for use by HOPDs and ASCs. For example, the American College of Surgeons’ (ACS) National Surgical Quality Improvement Program (NSQIP) has been developing and testing a survey that incorporates six existing PRO (34 questions total). We urge CMS to proceed with caution when considering whether to implement one or more PROs in addition to the OAS CAHPS survey as part of the OQR and/or ASQR Programs, as it is highly likely that patients would be significantly burdened and confused by varying survey instruments, leading to lower response rates and less data and insights. Lastly, we refer CORE and CMS to CMS’s Blueprint for the Measures Management System (MMS), which is used to document “the core set of business processes and decision-making criteria for measure development, implementation, and maintenance”². Within the Blueprint, CMS</p>

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				<p>builds on their Meaningful Measures initiative from 2017, which aimed to improve outcomes for patients and families while reducing burden and aligning measures, among other goals. Administering the PRO-PM separately from the OAS CAHPS survey will do just the opposite—increase provider and patient burden and misalign measures. Requiring two survey-based measures would force providers to increase their investment in many ways, including hard dollar costs to administer an additional survey and an increased time commitment to learn about that survey instrument and monitor performance. If CMS truly aims to reduce both patient and provider burden, reduce costs, and align measures for a streamlined approach to data collection, reporting, and improvement, combining the measure concepts of this PRO-PM into the OAS CAHPS survey is a prime opportunity to do just that.</p> <p>FUTURE CONSIDERATIONS Press Ganey strongly supports patients and families, and their ability to have the information needed to make informed choices about where to seek care. We support transparent and public access to health care quality data, including the data found on Medicare’s Care Compare and Provider Data Catalog websites. Currently, OAS CAHPS data collected for HOPDs and ASCs participating in the official, voluntary administration of the survey is reported on the Provider Data Catalog. When OAS CAHPS becomes mandatory for HOPDs and ASCs in 2024 and 2025, we encourage CMS to report the data in a more user-friendly manner on the Care Compare website. If the PRO-PM measures were to be incorporated into the OAS CAHPS survey in the near future, those measures would also be included in public reporting. Additionally, by the nature of public reporting the measures, HOPDs and ASCs will be encouraged to perform well on those measures, thereby increasing performance, reflected by patients’ reported understanding of information about their recovery process and improved outcomes –the primary goal of the PRO-PM. Finally, because the OAS CAHPS survey will soon be a required measure for HOPDs and ASCs, incorporating the PRO-PM measures to OAS CAHPS would automatically apply the PRO-PM themes to both settings.</p> <p>Conclusion As illustrated above, the PRO-PM and OAS CAHPS would overlap in survey content, cohort, and administration. This would increase survey fatigue among an already-fatigued patient population. As a result, we urge CMS to incorporate the PRO-PM measure concepts into the existing OAS CAHPS survey. Press Ganey would like to thank CORE and CMS for this opportunity to provide input on the project.</p>

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11	April 11, 2022	Patricia L. Turner, MD, MBA, FACS, American College of Surgeons		<p>1. Patient Reported Outcome – Performance Measures (PRO-PM) Should More Closely Align with Patient Goals of Care Overall, ACS commends CORE & Centers for Medicare and Medicaid Services’ (CMS) efforts to develop and incorporate patient reported outcomes (PROs) and patient experience measures into federal quality programs. However, we seek further information on what the goal is for gathering the information specified in this measure, as well as what is planned for the information once it is collected, and how it will be used to drive improvement in surgical care. ACS is concerned that this will become another burdensome data collection tool that will not result in meaningful change without a clear plan for how the survey data will be used to inform quality improvement cycles and help patients make decisions about their care. We encourage CORE to investigate whether there are more targeted and meaningful survey questions for patients recovering from outpatient surgery and/or procedures. We assert that aligning the survey questions to focus on shared decision-making, identifying patients’ goals, and understanding if the goals were achieved will be more meaningful to patient outcomes. We also note the low response rate of the survey and question whether that may have been a result of survey burden and lack of meaningful engagement. If the survey incorporates questions that the patient views as more meaningful, completing the survey may feel less burdensome and patients may be more motivated to respond if they feel heard. ACS suggests that the survey be refined to include more meaningful, targeted questions so patients do not feel overwhelmed by the length of the survey.</p> <p>2. Suggest Reclassification of the Measure from PRO-PM to Patient Experience Quality measures that seek the patient’s voice about functional components of their post-operative recovery is a step in the right direction towards PROMs that assess important outcomes, such as whether the operation met the patient’s goals for having surgery. ACS has committed to working on ways to spur the transition to value-based care and continues to work on and think about opportunities to highlight the patient’s voice in value-based models for surgical care. From ACS’ perspective, value should be defined by what is most important to the patient and this can be done by using PROMs that recognize if patients’ goals for care were first identified and then if they were ultimately achieved, as mentioned above. However, as written, the “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure” measure serves primarily as a process attestation rather than a measure that evaluates if a patient’s desired outcome is achieved. The survey focuses more on processes, structural elements,</p>

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				<p>and environment. Given this, we believe that this measure is misclassified as a PRO, and in fact the survey is better classified as a patient experience measure. Evaluating structural elements of care and understanding patient experiences are important factors that can be used to inform and improve care processes. However, we suggest that if CORE’s goal is to better understand patient outcomes, more focus should be put on how the patients’ functional goals and overall goals of surgery were met, and surveys should be distributed two to four weeks following surgery. Currently, the survey is distributed seven days following a surgery or procedure, and this does not allow enough time to capture any longer-term effects from surgery. Most patients are still recovering seven days after surgery.</p> <p>It is also important to note that PROM development is still in nascent years and there is much more we must study to better understand the impact they might have. Critical to this is also building the data infrastructure to make patient data collection less burdensome.</p> <p>3. Missing Opportunity to Focus on Equity in Surgical Care CORE asks for feedback on additional risk variables that they should consider in the measure methodology. In reviewing this measure, we believe there is a missed opportunity to advance health equity. Equity and inclusion are important factors to consider in quality measurement, but especially in PROMs and patient experience measurement, where the data are being gathered directly from the patient. From ACS’ perspective, it is important to recognize that social factors and other distinctions among the patient cohort can have a direct impact on patient responses and overall response rates. In ACS’ quality programs, we have been considering how to measure inclusion. Inclusion is an area of health care that still needs development and encompasses the patient’s feelings about if they received care that is sensitive to their culture, beliefs, language, race, ethnicity, sexual orientation and gender identification, personal circumstances and so on. Inclusion should also account for whether patients feel they are in an environment where they are understood, have a feeling of trust, and can be connected to community-based organizations or other resources they need to optimize their goals of care.¹ This can help clinicians understand if the patient feels a sense of trust with their care team, and/or where there are gaps that can be improved upon. As CORE works to refine this measure, we encourage the measure developers to consider how they can align elements of inclusion and equity with the survey questions.</p> <p>We also ask the CORE team to explore how representative the sample is of a diverse</p>

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				<p>population of surgical patients, and whether the patient cohort may have impacted response rates—for example, were there differences based on race, ethnicity, or socioeconomic factors for those who responded to the survey—or did they not respond? If response rates are low in a certain patient population, the PROM data may help to understand the low response such as language barriers, health literacy, access to Wi-Fi, and geographic location, to name a few. This can help health care organizations learn more about the needs of the patients surveyed (or what patient groups were not represented in the survey). ACS suggests that CORE first start by considering characteristics that should be assessed for equitable care and then determine how these can be incorporated in the survey, as mentioned.</p> <p>4. Major/Minor Surgical Procedure Distinction CORE uses the global payment periods to categorize major and minor outpatient surgeries and procedures. A major procedure is defined by having a 90-day follow-up period and a minor procedure is defined by a zero to 10-day follow-up period. CORE could maintain the process of using global periods to make distinctions between major and minor surgeries. Once the surgeries are classified, we recommend retaining all major procedures, but then evaluating the minor procedures to determine if the procedure would be so minor that the survey is not appropriate. This evaluation could be done with the help of subject matter experts to determine what procedures should be included and excluded from the measure. For example, a procedure, such as an excision procedure for lymph nodes, would be classified as minor but given the nature of this procedure, a targeted PROM could help patients and surgeons understand the outcomes and opportunities for improvement.</p> <p>In addition to reviewing the complexity, we also recommend that CORE create a list of the commonly performed procedures based on their global period (or major/minor distinction).² The PRO efforts should also be applied to inform those procedures that cross a “commonly performed threshold.” Identifying commonly performed procedures will likely contribute to a reasonable rate of return and help create targeted improvement cycles for these procedures. Ultimately, it is important to ensure that the use of PROs fits within the clinical purpose and is not predicated on billing practices.</p> <p>Finally, the measure developers ask for feedback on how they can implement the survey. Specifically, they discuss the possibility of specifying the measure in Fast Healthcare Interoperability Resources (FHIR) and using Application Programming Interfaces (APIs) to gather data needed to define the measure cohort and other</p>

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				<p>measure-related data. Since the onus is on the patient to respond to the survey, we recommend that CMS and the measure developer investigate patients’ preferences for engagement. There are many ways to distribute surveys, such as text message, email, mobile applications, patient portals, paper, etc., but if the patient views the data collection method as inconvenient and burdensome, they will be less likely to respond.</p> <p>The ACS appreciates the opportunity to provide feedback on this measure and looks forward to continuing dialogue with CORE and CMS on ways to develop meaningful PROs for surgery. If you have any questions about our comments, please contact Jill Sage, Chief of Quality Affairs, at jsage@facs.org.</p>
12	April 11, 2022	Andrew B. Bindman, MD, Kaiser Permanente	Healthcare System	<p>Kaiser Permanente¹ appreciates the opportunity to provide comments on the development of the novel Patient-Reported Outcome-based Performance Measure (PRO-PM), entitled “Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure” focused on the effective transfer of clinical information from provider to patient after an outpatient procedure or surgery.</p> <p>The Kaiser Permanente Medical Care Program is the largest private integrated health care delivery system in the U.S., with more than 12.5 million members in eight states and the District of Columbia. Kaiser Permanente exists to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.</p> <p>We appreciate CORE’s efforts in developing this PRO-PM, but we have a few concerns with respect to issues of Survey Instrument, Measure Cohort, and Survey Implementation.</p> <p>First, we are concerned that the proposed PRO-PM measures the same construct (recovery) that is already incorporated within the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS-CAHPS), specifically the discharge and recovery composite. While the questions differ, the underlying construct is similar. The PRO-PM under development asks the patient to respond to questions about the appropriateness and clarity of discharge instructions for recovery. The OAS-CAHPS survey asks the patient to respond to questions about specific recovery outcomes (nausea, vomiting, bleeding, etc.) and whether they were provided information about those potential post-operative outcomes.</p> <p>Second, we have concerns that the implementation may place an additional burden on patients. Asking patients to complete two surveys (PRO-PM and OASCAHPS) for</p>

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				<p>the same episode of care, and targeting the same information, can have an impact on who responds to each survey and on the response rates for both surveys. The level of sample representativeness and the response rate can be especially impacted for whichever survey is fielded last. Finally, we are concerned the current methodology places a burden on hospital outpatient departments and ambulatory surgery centers to collect patients' consent to be surveyed, especially those with high volumes of surgeries and procedures. The current process places the burden on facility staff to ensure consent protocol is followed properly, as it requires staff to review every intake form for consent.</p> <p>Kaiser Permanente appreciates CORE's consideration of our comments and would be pleased to discuss these issues with CORE in more detail as the measure is further developed. Please contact me at andrew.b.bindman@kp.org or Keavney Klein at keavney.f.klein@kp.org if we can provide further information or answer any questions.</p>
13	April 11, 2022	David Orr, Senior Director, Cleveland Clinic	Healthcare System	<p>Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching, and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 19 hospitals with more than 6,400 staffed beds, 21 outpatient Family Health Centers, 11 ambulatory surgery centers and numerous physician offices. Cleveland Clinic employs over 5,000 salaried physicians and scientists. Last year, our system cared for 2.9 million unique patients, including 10.2 million outpatient visits and 304,000 hospital admissions and observations.</p> <p>Cleveland Clinic appreciates the opportunity to provide feedback on the development of a patient-reported outcome performance measure for the effective transfer of clinical information from provider to patient after a procedure or surgery, for use in the quality measurement of Hospital Outpatient Department (HOPD) and Ambulatory Surgical Center (ASC) settings. Overall, we believe support the development of this measure as its concept is reasonable and we find it aligns well with the HCAHPS measures for acute care patients in the inpatient setting. We have a few brief recommendations that could improve the measure, described below.</p> <p>Survey Instrument Though the survey asks whether instructions were given before the surgery or procedure, we recommend incorporating new or revised language that better reflects best practice. Language such as "Education was provided to me in my doctor's office before the day of my surgery or procedure" indicates that some form of significant education beyond mere instruction was provided before the</p>

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				<p>patient shows up on the premises where the procedure will take place.</p> <p>Risk Adjustment Given our suggestion above, some means of risk stratification based on procedure type should be considered. More complex procedures, such as total knee replacements, may entail more intense education and detailed information provision than others to facilitate patient understanding of results and recovery. In addition, the measure should ensure that the full range of social determinants of health (such as poverty level, employment status, education, urban vs. rural, race, ethnicity, access to care, among others) is incorporated into the risk adjustment.</p> <p>Survey Implementation The methodology report currently states an additional pilot of the survey would be implemented via e-mail or text, much like the first pilot. Given the intent to expand the survey sample size significantly, we suggest broadening the spectrum of available communication platforms to better accommodate the multitude and diversity of patients that will be surveyed. We also encourage that FHIR standards for interoperable data be leveraged to facilitate survey implementation such that it reduces provider and patient burden.</p> <p>Thank you for conducting a thoughtful process that allows us to provide input on this important issue and for your consideration of this information. Should you need any further information, please contact David Orr, Senior Director, Enterprise Safety and Quality, at ORRD3@ccf.org</p>
14	April 11, 2022	Randall M. Clark, MD, FASA, American College of Anesthesiologists	Medical associations and societies	<p>Dear Yale – CORE,</p> <p>On behalf of the 55,000 members of the American Society of Anesthesiologists® (ASA), I am pleased to offer feedback and comments on the Yale New Haven Health Services Corporation – Center for Outcomes Research & Evaluation (YNHHSC/CORE) Patient Understanding of Key Information Related to Recovery from an Outpatient Surgery or Procedure Patient Reported Outcome – Performance Measure (PRO-PM). We support the development and implementation of this patient reported outcome measure as it will allow patients to provide their assessment of the care, they received during an outpatient procedure.</p> <p>Physician anesthesiologists are an integral piece to the perioperative episode of a patient, especially in outpatient settings. Despite the implementation of Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Hospital-CAHPS, there is a persistent gap in the ability for physicians to adequately measure patient experience based upon commonly used quality measures for performance-based payment programs. To provide high quality, patient-centered care in the future, anesthesiologists and other qualified anesthesia professionals should have the</p>

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				<p>opportunity to objectively measure and assess the patients' perceptions of the care they received. Anesthesiologists want to understand whether the patients felt they were treated as individuals and empowered by their anesthesiologists to engage in decision-making. The assessment of patient satisfaction, especially with anesthesia care, allows anesthesiologists, the patient's care team, and other stakeholders to identify gaps in care and, using that data, work to achieve high patient satisfaction scores. At present, there is an array of patient satisfaction tools for practices and individuals to use based upon local patient populations and local quality improvement initiatives. However, an overall patient satisfaction survey at the physician or group level remains a significant gap in measurement.</p> <p>We offer a few areas of clarification related to the refinement of the patient survey and the patient cohort. We appreciate the opportunity to provide this feedback.</p> <p>Survey Instrument: ASA supports the overall survey design, but we are concerned about survey fatigue among patients. The domains addressed in the survey cover the spectrum of topics needed to collect essential details from the patient. While there are 12 survey questions on the surface, several questions branch into multi-part response requests. We believe those follow-up questions are important information to collect, but we suggest Yale-CORE consider how best to mitigate potential survey fatigue. We first suggest Yale-CORE condenses questions based on the electronic responses captured from the patient. For example, in question number 4, "How clear was the information about when and why to start medications and potential side effects?" We believe if the patient answers less than "very clear," the respondent should be asked additional questions to elicit which features of this aspect of their care impacted their assessment. Second, we suggest Yale-CORE eliminate the "About you" section since the majority of this patient information would have already been captured electronically, either in the electronic health record (EHR) or linked from the information the patient provided at the time of admission or when scheduling the procedure. Regardless, the survey will provide essential information from the patient that may not otherwise be captured.</p> <p>Risk Adjustment: ASA agrees with the Risk Adjustment design that seeks to ensure that survey results reflect, as best as possible, the true nature of the care that patients received. This type of data collection and risk assessment is essential to capture a broad scope of patient assessments for procedures taking place across hospital outpatient settings and ambulatory surgery centers. We believe Yale-CORE</p>

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				<p>and other measure developers can use appropriate and meaningful risk adjustment algorithms that could shed greater light on health disparities. The addition of census data may aid in the risk adjustment model to address social determinants of health information that may not be readily captured.</p> <p>Measure Cohort: ASA supports the target population as all patients (except those receiving procedures in an emergency department) 18 years and older. A larger sample size of patients, especially those across payers, including Medicaid, will lead to gathering key information, such as patient understanding of medical instructions in their recovery following surgery. By including a more extensive, rather than limited, types of cases, anesthesiologists will have greater opportunities to improve their care. Yale-CORE should not limit the scope of the measure to a limited number of major or minor surgeries as defined by CMS.</p> <p>Survey Implementation: We agree that a third-party implementation of this patient survey would reduce burdens placed on anesthesiologists and their groups. As previously mentioned, integrating vital information from the EHR or other intake processes would save time for the patient and could lead to a higher response rate among patients. We also suggest Yale-CORE test the elimination of redundant or patient demographic questions. ASA members have worked with a number of survey vendors and electronic apps. We are optimistic that this measure can be securely implemented via electronic means in a way that prevents further health care burden and mitigates survey fatigue.</p> <p>Thank you for your consideration of our comments. We welcome the opportunity to speak with you further about our feedback in the future. Please contact Claire Ostarello, ASA Senior Quality and Regulatory Affairs Associate (c.ostarello@asahq.org), for questions or further information. Sincerely, Randall M. Clark, MD, FASA President American Society of Anesthesiologists</p>
15	April 11, 2022	Bob Blancato, Defeat Malnutrition Today (DMT)		<p>Defeat Malnutrition Today (DMT)* appreciates the opportunity to comment on the novel patient-reported outcome performance measure (PRO-PM). We comment specifically on the importance of assessing patient education measures in older adults with malnutrition.</p> <p>In the Call for Public Comment, CMS states it is developing a performance measure to assess patient understanding of information related to recovery from an outpatient surgery or procedure. CMS also requests feedback on potential refinements to the survey instrument, the measure’s risk-adjustment model, the measure cohort, survey implementation, and possible measure use for hospital-</p>

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				<p>based outpatient department and ambulatory surgical centers.</p> <p>We commend CMS for focusing on patient understanding of medical information to facilitate improved care and lead to better immediate outcomes. Understanding and following health education material continues to be a challenge for older Americans. Older adults are particularly at risk because of low income, mobility issues, dementia, and other factors such as social isolation.</p> <p>Risk-adjustment Model Defeat Malnutrition Today supports including malnutrition status in the risk-adjustment model of the PRO-PM. Many patients are malnourished or at risk for malnutrition upon hospital admission, with their nutrition status often deteriorating during hospitalization. Up to half of all older adults are at risk of malnutrition. In the acute care hospital setting, for example, it is estimated that approximately 20 to 50 percent of admitted older patients are malnourished or at-risk of malnutrition and often discharged without a malnutrition diagnosis.^{1,2} Older adults are uniquely at risk for rehospitalization and poor surgical outcomes and should be. Malnutrition risk assessment can be determined through short questionnaires like Malnutrition Screening Tool.³</p> <p>In summary, many older adults are at risk for malnutrition or are malnourished, and we urge you to not exclude malnutrition from your risk-assessment model. Further we agree that assessing and improving patient understanding of information is timely and important.</p> <p>Thank you for considering our comments. Please let us know if we can provide you with any further information. You may reach me at rblancato@matzblancato.com. Sincerely, Bob Blancato National Coordinator Defeat Malnutrition Toda</p>

Appendix B: Survey Instrument

Introduction

This is a short, multiple-choice question survey that should take you 5-7 minutes to finish.

You are getting this survey because you recently had a surgery/procedure. You should have been given information before and/or after your surgery/procedure about what to do during your recovery process. We would like to know if this information was clear and easy-to-follow. Your answers will help other patients like yourself be more informed about their recovery.

Neither your name nor any other identifying information will be shared with your provider if you decide to respond to this survey. This survey can be filled out by you or your caregiver.

Main Source(s) of Information

When answering the survey questions please think about **all the information** you were given about your surgery/procedure, from the day you decided to get your surgery/procedure until now.

Q.1 - Select **all** the sources of information you used/are using for your recovery:

- Instructions given **before** your surgery/procedure
- A conversation about your surgery/procedure **in the recovery room**
- Instructions given **when you were sent home** from your surgery/procedure
- A **follow-up** visit or phone call
- Other (family, friends, medical website, Google, message boards, etc.)
- None of the above

General Information

Q. 2 -The information you got about your recovery helped you:

- 2a. Understand what to expect
 - Yes
 - Somewhat
 - No
- 2b. Easily know what you needed to do each day
 - Yes
 - Somewhat
 - No
- 2c. Answer questions you may have had
 - Yes
 - Somewhat
 - No

Information was Applicable to Me

Q. 3 - The information you got about your recovery considered:

- 3a. Your health needs (any/all medical conditions, pain management, treatment preferences, etc.)
 - Yes
 - Somewhat
 - No
- 3b. Your personal situation (transportation needs, insurance coverage, financial status, etc.)
 - Yes
 - Somewhat
 - No
- 3c. Your home/community environment (presence of caregiver(s), obstacles like stairs or wheelchair accessibility, walkability of your neighborhood, etc.)
 - Yes
 - Somewhat
 - No

Medications

Q.4 - How clear was the following information about your recovery:

- 4a. **When** to start and stop any medications
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply
- 4b. **Why** you had to start or stop any medications
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply
- 4c. Potential side effects/interactions of new medications
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply

Warning Signs or Symptoms

Q.5 - How clear was the following information about your recovery:

- 5a. What were expected and unexpected symptoms
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply

- 5b. How and whom to contact in case of unexpected symptoms
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply

Daily Activities

Q.6 – How clear was the following information about your recovery:

- 6a. Changes to your diet
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply
- 6b. Changes to physical activities, including exercise
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply
- 6c. When you could return to work
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply
- 6d. When you could drive
 - Very clear
 - Somewhat clear
 - Not clear
 - Does not apply

About You

Q.7 - Are you the patient or a caregiver?

- Patient
- Caregiver

Q.8 - In the past 5 years how many surgeries/procedures have you had (not counting this one)?

- 0
- 1-3
- 4+

Q.9 - In general, how would you rate your overall health?

- Excellent
- Very good
- Good
- Fair
- Poor

Q.10 - What is the highest grade or level of school that you have completed?

- 8th grade or less
- Some high school, but did not graduate
- High school graduate or GED
- Some college or 2-year degree
- 4-year college graduate
- More than 4-year college degree

Q.11 - Which of the following do you identify as? **You can select more than one category.**

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or other Pacific Islander
- White or Caucasian
- Prefer not to answer

Q.12 - What language do you mainly speak at home?

- English
- Spanish
- Other