ENHANCING ONCOLOGY MODEL

EOM ELECTRONIC PATIENT-REPORTED OUTCOMES GUIDE

Version 2.0

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Revision History

Revision #	Revision Date	Description of Change
1.0	6/20/2023	Initial Version
2.0	11/29/23	1. Updated Section 1. 2. Updated Section 2. 3. Updated Section 3. 4. Updated Appendix A. 5. Added Appendix B to include additional key terms. 6. Added Appendix C to include an example checklist for preparing for ePROs implementation.

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Introduction and Rationale for ePROs Implementation

This document is designed to guide Enhancing Oncology Model (EOM) participants in the gradual implementation of collecting electronic patient-reported outcomes (ePROs), one of eight required participant redesign activities (PRAs).

EOM is a Center for Medicare & Medicaid Innovation (Innovation Center) alternative payment model designed to promote high-quality, person-centered care, advance health equity, promote better care coordination, improve access to care, reduce costs, and improve outcomes for Medicare fee-for-service (FFS) beneficiaries with cancer who receive an initiating cancer therapy. EOM builds on lessons from the Oncology Care Model (OCM) and shares certain features with OCM, including episode-based payments that financially incentivize physician group practices (PGPs) to improve care and lower costs. EOM participants are oncology PGPs that prescribe and administer cancer therapy for included cancer types, and the model is centered on 6-month episodes of care triggered by receipt of an initiating cancer therapy for an included cancer type. Seven cancer types are included in the model:

1. breast cancer [a]
2. chronic leukemia
3. lung cancer
4. lymphoma
5. multiple myeloma
6. prostate cancer [a]
7. small intestine / colorectal cancer

In alignment with the Centers for Medicare & Medicaid Services' (CMS') commitment to reducing health disparities and achieving health equity in CMS quality programs and within Innovation Center models, EOM is designed to advance health equity within all stages of model design, implementation and evaluation and aims to improve quality of care and equitable health outcomes for all EOM beneficiaries.[1,2] Beneficiary sociodemographic factors influence health outcomes.[3,4] Disparities in cancer care based on sociodemographic status can occur throughout the cancer diagnosis and treatment trajectory, including, but not limited to, the timing of the start of treatment, stage at diagnosis, representation and access to clinical trials, shared decision making with providers, medication adherence, hospitalizations and ICU admissions near the end of life, and enrollment in hospice.[5,6,7,8]

Under terms of the Participation Agreement (PA), EOM participants are required to implement eight participant redesign activities (PRAs) (**Figure 1**). In alignment with CMS' commitment to focusing on whole-person care, EOM is designed with patient-centeredness at the forefront. To that end, one PRA required of EOM participants *is gradual implementation of collecting and monitoring electronic patient-reported outcomes (ePROs) for eligible EOM beneficiaries*. Patient-

[a] Low-risk breast cancers and low-intensity prostate cancer are not included in EOM. For the purposes of EOM, low-risk breast cancer is defined as breast cancer treated with only long-term oral endocrine therapy; and low-intensity prostate cancer treated with either androgen deprivation and/or anti-androgen therapy without any other chemotherapy.

reported outcomes are measurements based on a report that comes directly from the patient, without amendment or interpretation of the patient's response;[9] ePROs are the electronic capture of this data.[10]

Figure 1. EOM Participant Redesign Activities (PRAs)

The collection and use of ePROs tools in oncology settings can lead to:

- Increased patient self-awareness of symptoms;
- Improved communication between patients and care teams;
- Increased ability to monitor symptoms longitudinally;
- Increased feeling of involvement of patients in their care;
- More open and honest discussions around symptom management;
- Better identification of patients' needs;
- Higher patient satisfaction with care experience and improved quality of life; and
- Improvements in cancer outcomes, such as decreased emergency department visits, hospitalizations and, in several studies, improved survival among certain cancer types.[11,12,13,14,15,16,17,18]

ePROs can also aid both process and outcome quality improvements, including clinician awareness of concerning changes in a beneficiary's clinical status on a timely basis, translating to improved survival outcomes when part of oncology treatment.[19,20,21] The COVID-19 public health emergency has emphasized the need for additional beneficiary-reported data outside of in-person visits, as demonstrated by the increased uptake of telehealth and remote communication technologies.[22,23,24,25]

The following sections of this guide provide more detail about the EOM ePROs implementation:

- **Section 1** provides considerations for ePROs implementation, including ePROs standard domains, EOM graduated ePROs implementation timeline, and frequency and method of ePROs administration.
- **Section 2** provides an overview of emerging tenets for successful ePROs implementation in oncology.
- **Section 3** provides a list of additional EOM resources.

Section 1: ePROs Implementation Considerations

1.1 ePROs Survey Standard Domains

CMS does not currently require use of a specific ePROs survey. Instead, CMS has outlined defined domains and standards for use of ePROs under EOM to ensure the use of high-quality surveys and to help meet EOM's goal of improved care quality. Prior implementation research and clinical guidelines provide additional details on the validity and reliability of items administered and these references are included in **Section 3: Additional EOM Resources**. The use of defined domains preserves flexibility and allows for new ePROs development, as well as the use of existing ePROs tools and instruments that may already be in use by EOM participants prior to EOM start.

EOM participants are required to use ePROs surveys that capture, where applicable, beneficiary-level outcomes for each of the following domains at a minimum:

- Symptoms and/or symptomatic toxicities
    - Individual evaluation of symptoms that are common across cancer types, for example: anorexia (appetite loss/decreased oral intake), constipation, diarrhea, dyspnea, mucositis, nausea, pain, sensory neuropathy, sleep disturbance, vomiting.[26]
- Functioning
    - Physical functioning, role functioning (e.g., activities of daily living (ADLs) or instrumental activities of daily living (IADLS))
- Behavioral health
    - Anxiety, depression, other behavioral health concerns
- Health-related social needs
    - Financial distress/toxicity, transportation insecurity, food insecurity, housing instability

While several terms and definitions are used to discuss the social determinants of health (SDOH), CMS has most often referred to individual-level non-clinical needs that are identified through screening in a clinical setting as health-related social needs (HRSNs). HRSNs are the adverse social conditions that negatively impact a person's health or health care.[27,28] Where SDOH are the structural and contextual factors that shape a person's life, HRSNs are individual level factors, such as, challenges in obtaining proper nutrition during cancer treatment, access to transportation for infusion appointments, or housing insecurity, which can affect receipt of cancer are or outcomes. HRSNs impact the health and well-being of many Medicare beneficiaries with cancer and pose a risk of exacerbating health disparities if not identified and mitigated, for example, referrals and other patient navigation efforts.[29,30]

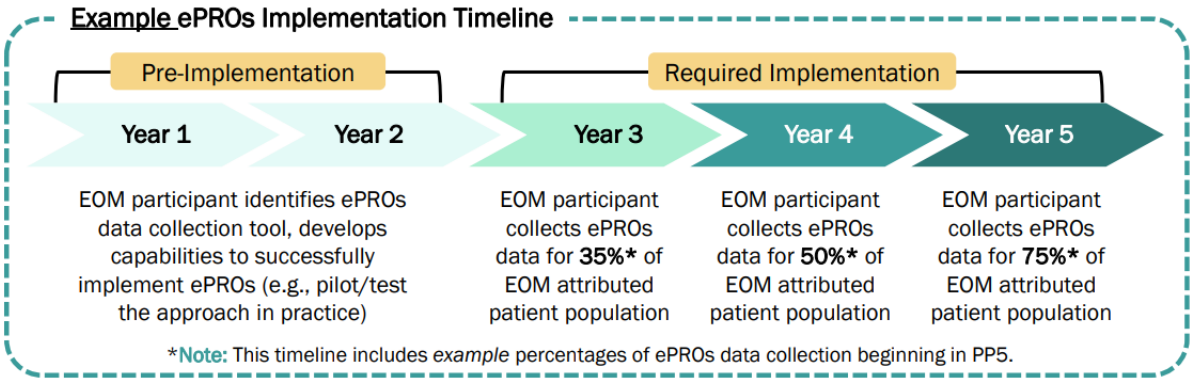
EOM participants are encouraged to use patient-first language with their beneficiaries, for example, "financial toxicity" is a term more commonly used in academic settings, whereas the term "financial distress" is often used with patients. For more information on the health-related social needs requirement, please see the EOM Health-Related Social Needs Guide.

These domains represent areas for potential quality improvement in oncology service delivery. Specific examples of ePROs surveys that can be used to collect this information are provided in **Section 2.2: ePROs Survey Selection**. CMS encourages the use of non-proprietary[b] ePROs surveys (e.g., PRO-CTCAE or PROMIS) to further transparency and consistency across CMS models and programs. In line with CMS's focus on achieving health equity, EOM participants should consider ePROs surveys that have been previously tested and shown to be valid and reliable in diverse populations (e.g., linguistic, and culturally relevant ePROs surveys, including but not limited to: PRO-CTCAE which is offered in more than 50 languages[31] and EORTC QoL which is offered in more than 120 languages).[32]

1.2 ePROs Implementation Timeline in EOM

This section provides an overview of the ePROs implementation timeline required of EOM participants. EOM participants will implement ePROs capabilities in a stepwise manner over the course of the model. **Figure 2** provides an example ePROs implementation timeline, including an overview of pre-implementation and required implementation expectations. This timeline includes *example* percentages of ePROs data collection beginning in Performance Period (PP) 5. Note that at this time, these percentages are examples, with the intent for EOM participants to gradually increase the uptake of ePROs over time. More information on the requirements for implementation are forthcoming.

Figure 2. ePROs Implementation Timeline



EOM year 1 (PP1 and PP2) and year 2 (PP3 and PP4) will be optional pre-implementation years for ePROs, during which EOM participants will develop the capabilities necessary to successfully implement ePROs in a manner consistent with the standard domains and implementation requirements. Beginning in model year 3 (PP5 and PP6), gradual implementation of ePROs will be required of all EOM participants.

EOM participants are required to obtain standardized beneficiary-level ePROs response data from an increasing percentage of beneficiaries each model year, beginning with model year 3 (e.g., 35 percent, 50 percent, 75 percent). EOM participants will engage with patients through gradual

[b] For any ePROs surveys (e.g. PRO-CTCAE or PROMIS), EOM participants should check with organizations that manage each tool for rules concerning modifications and use.

implementation of ePROs to better identify patients' needs, improve patient-provider communication, care management, patient satisfaction, and cancer outcomes. Engagement with patients through ePROs data collection can also aid process and quality improvement, including clinical awareness of concerning changes in a patient's clinical status on a timely basis. EOM participants are expected to increase engagement over time (e.g., increased patient enrollment, timely follow up with patients, monitoring symptom reports, tracking alert notifications, and more). CMS is taking a gradual implementation approach from optional data collection to required data collection to provide flexibility for EOM participants with and without experience with ePROs. This approach also allows for the necessary time to adjust workflows and technology to integrate this important enhanced service into clinical care delivery. Once ePROs data collection is mandatory, EOM participants will also be required to integrate ePROs data into their information system workflow. Ideally, this will include some level of integration with electronic medical records (EMRs), for example, by visualizing ePROs data in the EMR, identifying eligible patients for ePROs participation, documentation of ePROs data, and/or communication about the ePROs data between providers.

We acknowledge logistical challenges, such as technical design and workflow configuration, and are sensitive to potential costs associated with an ePROs integration requirement. We believe that data that are readily available, integrated into the workflow, and easy to view are more actionable and lead to improved patient outcomes. Integrating ePROs within EMRs has facilitated symptom reporting, automated triage, and referral for psychosocial and supportive care as well as improvements in standardized care and workflow.[33,34]

Acknowledging the current diversity in ePROs surveys available, emerging standards, and the varying degree to which oncology practices have implemented these surveys to date, ***EOM participants are not currently required to submit ePROs data (i.e., the results of ePROs surveys themselves) to CMS.*** However, as the ePROs field progresses, and CMS assesses the implementation of ePROs under EOM, we may require that EOM participants report ePROs data to CMS in later performance periods.

During participation in EOM, practices may be asked to submit documentation, feedback and/or additional information about implementation of ePROs, as described in the EOM PA in Article VII, Section 7.2 and Appendix B. Should an EOM participant be selected for a monitoring site visit, an EHR audit may be performed as part of the monitoring visit for CMS to validate that ePROs data are being collected. Participants may be asked to share additional information with CMS, such as describing how ePROs implementation is progressing as well as any best practices or challenges with implementation.

1.3 Frequency and Method of ePROs Administration

The first step to implement ePROs is through integration in EOM participant workflows, as assessed by engagement between the EOM participant and EOM beneficiaries. EOM participants must collect ePROs data from each eligible EOM beneficiary *a minimum of once before each visit where one or more qualifying evaluation and management (E&M) services are furnished to the EOM beneficiary during an episode* (except for the beneficiary's first visit with the EOM

participant). Additional ePROs administration may vary depending on beneficiary need. Some past ePROs programs and research have demonstrated the benefits of beneficiaries completing ePROs surveys on a regularly scheduled basis, for example weekly from home.[35,36]

In addition to the gradual implementation of ePROs, another PRA requirement is the use of established, validated screening tools to collect health related social needs (HRSNs) data from EOM beneficiaries and to develop a plan for addressing those needs. EOM participants are required to use ePROs surveys that capture, where applicable, beneficiary-level outcomes for four required domains, one of which is HRSNs. For the HRSN screening requirement, EOM participants are expected to screen each EOM beneficiary, at a minimum, once per performance period. EOM participants should consider if additional screening is necessary, based on beneficiary need. For ePROs collection requirements related to HRSN screening requirements, at a minimum, EOM participants have the option to conduct a full HRSN screening at each E&M visit or to conduct a full HRSN screening once every 6 months. Should an HRSN screening only be conducted once every 6 months, the EOM participant should ask the EOM beneficiary at each E&M visit if there have been any changes from the previous visit in their needs around food, transportation, and housing.

EOM participants are not required to collect ePROs data in advance of the first visit or during the first visit. Rather, EOM participants should use this first visit to introduce and discuss the benefits and/or logistical details of using ePROs with the EOM beneficiary. The ePROs questions may be administered at any point prior to the qualifying E&M service via an electronic format, including, but not limited to:

- Web-based remote access,
- Interactive voice response systems (i.e., automated telephone systems),
- Screen-based reporting devices (e.g., smartphones),
- SMS text systems,
- In the waiting room immediately before the appointment (e.g., by tablet computer or kiosk), and,
- Telephone interviews by a staff member with data entry into the ePROs system.

Paper surveys are not favored as a primary means to collect ePROs, because this approach will require subsequent manual data entry and can introduce errors. Additionally, compliance cannot be monitored easily or in real-time.[37] However, paper surveys with real time data entry can be considered as a backup data collection approach for patients unable to report other ways. Back up data collection approaches may also include staff administered surveys via tablets or kiosks.

To reduce EOM beneficiary burden, ePROs assessment duration for patients should be brief, for example no longer than 10 minutes per assessment. This translates into fewer than about 20 questions per assessment. EOM participants are expected to review EOM beneficiary ePROs responses with the beneficiary at each visit during which a qualifying E&M service is furnished.

Section 2: Emerging Tenets for Successful ePROs Implementation

To guide practices with design and implementation strategies, key tenets have been developed from prior ePROs program experiences and research.[38] Successful implementation of ePROs data collection helps ensure the full benefits of a symptom monitoring program are received by the beneficiary and clinical care team. Essential tenets for EOM participants to consider implementing relate to the following areas:

- software function,
- survey selection,
- alert notifications,
- clinical and non-clinical staffing,
- patient engagement and equity, and
- commitment and sustainability.

Each of these tenets is discussed in detail below.

2.1 Software Function

ePROs software can be free-standing or can be integrated with other practice information systems such as the EMR, symptom management/triage software, and/or patient portal. EOM participants should use ePROs data collection surveys that incorporate key interface features for the patient, care team, and administrative staff, as described below.

2.1.1 Patient Interface

An effective patient interface should be simple to use and access for a variety of beneficiaries. Some considerations for key features are:

- Screen visualization:
  - Easy-to-read text (font & size)
  - Clear and concise instructions in plain language
  - User-friendly page design
- Functionality
  - Ability to complete an ePROs survey via computer, smart device, and/or automated telephone system
  - Electronic prompts for remote ePROs monitoring programs via email, text message, EMR portal message, or automated telephone call
  - Direct links to surveys with password-less or one-time password access
  - Survey offered in different languages

- Alert and Trending Capabilities
  - Ability to convey alert notifications to clinical care team electronically for worsening symptoms and/or urgent needs
  - Optional ability to view past and present self-reported symptoms to identify trends

2.1.2 Care Team Interface

The care team interface should allow for viewing of real-time alert notifications for urgent needs and worsening symptoms; and allow the care team to record actions in response to the notifications either in the ePROs software, other care management software (e.g., nursing triage software), or the EMR itself. The care team interface features should also include options to:

- Receive notifications through email, EMR, or secure messaging, with a link to a beneficiary's reported symptoms and/or concerns, contact information, and unique identifier to enable looking up the beneficiary in the EMR.
- Import ePROs data directly into clinical notes and messaging.
- Create user-friendly reports for the clinical care team and potentially the beneficiary.

2.1.3 Administrative/Staff Interface

The ePROs software's administrative/staff interface should include functioning for manual and automated enrollment of patients into the ePROs system, monitoring of enrollment at the practice and/or site level, functioning to monitor and assure that responses to alerts are documented by the care team, and response times are recorded and consistent with institutional goals for responding to beneficiary concerns that come through other channels such as voicemail or portal message. Some key features of this interface include enrollment options, alert notifications, and tracking of ePROs data collection. More details are included below in Table 1.

Table 1. ePROs Administrative Staff Software Interface: Recommended Enrollment, Notifications, and Tracking Functionalities

Enrollment Functionality	Notifications Functionality	Tracking Functionality
Registration of patients in monitoring program	Prompts and reminders for survey completion	Patient enrollment with self-reporting
Assignment of surveys specific to beneficiary information	Specified type of notification sent (email, shared in-basket, etc.)	Patient compliance with self-reporting
Automatic/Manual enrollment of beneficiaries	Updates on provider review (i.e., has the provider read/reviewed the alert notification?)	Metrics at patient and aggregate levels (i.e., dashboard)

2.2 ePROs Survey Selection

There are non-proprietary and established ePROs surveys and other resources available to EOM participants. These are examples only and do not constitute an endorsement by CMS or CMS affiliates. EOM participants have the flexibility to use other ePROs surveys as they see fit.

There are multiple well-established and tested sources for capturing symptoms in patient-reported outcomes monitoring programs, including, but not limited to:

- National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)[39]
- Patient-Reported Outcomes Measurement Information System (PROMIS)[40]
- Edmonton Symptom Assessment Scale (ESAS)[41]
- MD Anderson Symptom Inventory (MDASI)[42]
- European Organization for Research and Treatment of Cancer (EORTC) Quality of Life (QOL) item library[43]
- Patient Health Questionnaires (e.g. PHQ-2 and PHQ-9) for depression screening

There are additional resources available to support survey selection and clinical practice considerations related to PROs, including (but not limited to):

- The PROTEUS Guide to Implementing Patient-Reported Outcomes in Clinical Practice: A Synthesis of Resources (the PROTEUS-Practice Guide)[44]
- ESMO Clinical Practice Guidelines[45]
- Integrating Patient-Generated Health Data into Electronic Records in Ambulatory Care Settings: A Practical Guide[46]

For common outcomes, practices are discouraged from developing their own items, although creating items may be necessary for less common outcomes or questions about demographics. Items that have been used to assess physical functioning or frailty include (but are not limited to):

- Patient-reported Eastern Cooperative Oncology Group (ECOG) criteria[47]
- Comprehensive Geriatric Assessment Form[48]
- PROMIS Global-06 item from PROMIS global items[49]

There are non-proprietary and established HRSN screening tools available to EOM participants at no cost. These HRSN screening tools, presented in the EOM HRSN Guide and listed below, are examples only and do not constitute an endorsement by CMS or CMS affiliates. EOM participants have the flexibility to use other HRSN screening tools as they see fit. For any screening tools, EOM participants should check with organizations that manage each tool for rules concerning modifications and use.

Example HRSN Screening Tools:

- The NCCN Distress Thermometer and Problem List[50]
- Accountable Health Communities (AHC) Screening Tool[51]
- Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences (PRAPARE)[52]

For more information on the health-related social needs requirement, please see the EOM Health-Related Social Needs Guide.

2.3 ePROs Alert Notifications

Alert notifications should be triggered to the care team for any symptom reaching a concerning absolute threshold level of severity or with a meaningful worsening. Examples include:

- Setting an absolute threshold level for triggering notifications anytime a symptom is reported as severe or frequent on a verbal descriptor scale (such as the PRO-CTCAE) or reported at or above a certain numerical score (that may vary based on the survey or scale). For example, a numerical score of 6 on a 0-10 numerical rating scale, with a threshold for worsening being set at a 2-point increase on a 0-4 numerical, or verbal rating scale or a 3-point increase on a 0-10 scale; or
- Setting a lower threshold (will trigger more alerts): Setting the threshold for alerts to moderate (for example, if there are not accompanying alerts for worsening or in the postoperative setting where catching problems early is particularly desirable), or 5 on a 0-10 scale, or a 1-point increase on a 0-4 numerical or verbal rating scale, or a 2-point increase on a 0-10 scale.

Some providers implementing ePROs data collection have only included absolute thresholds for notifications and not worsening, which is discouraged, as many of the most clinically meaningful notifications are related to worsening of symptoms.[53]

Strategies to reduce the number of triggered notifications include assessing whether the patient's need can be addressed without an office visit, enabling clinicians to selectively turn off or pause specific notifications for specific beneficiaries (e.g., pausing diarrhea alerts for a beneficiary with known short bowel syndrome) to determine which problems are likely to lead to downstream complications, thereby warranting immediate action.

The number of notifications will depend on the selected thresholds, which can be adjusted if providers feel that it is appropriate for a given beneficiary population. Thresholds may be adjusted for specific symptoms, for example, higher thresholds may be appropriate for fatigue during chemotherapy because of high baseline prevalence. Lower alert thresholds will increase the number of alert notifications, so selection of alert thresholds should consider staffing capacity to field these notifications. Clinician and non-clinical staff responsible for addressing alert notifications should be prepared to respond to beneficiaries within one business day.

2.4 Care Team Staffing to Manage ePROs Data Collection and Notifications

An important element for success of an ePROs program is planning for staff deployment, roles and responsibilities, and engagement. Prior research suggests providing information on the value of ePROs monitoring for quality of care and patient centeredness may increase staff enthusiasm to participate and engage with ePROs data collection. Once providers and other care team members participate in ePROs data collection and follow-up, most recognize the value of symptom monitoring for care quality and efficiency.

Clinical staff (most commonly nurses and/or nurse navigators) and non-clinical staff (e.g., medical assistants, care coordinators, and other navigators) can support beneficiary engagement with ePROs data collection by:

- Inviting beneficiaries to participate in the data collection;
- Registering beneficiaries into the software system/survey;
- Assisting beneficiaries with training and onboarding to use the system/survey; and
- Providing beneficiaries with technical or logistical assistance.

In addition to supporting beneficiaries with system navigation, a key step to success and sustainability is planning for care team members to answer, triage, and manage increased messaging volumes. The care team should be designated and trained to receive and respond to alert notifications. The care team member(s) assigned to receive the alert notifications can vary based on the existing structure for fielding beneficiary voicemails or portal messages and symptom management.

To prepare for message volume increases, additional time may need to be set aside and protected for reviewing and addressing notifications. The volume of notifications will depend on the selected thresholds, which can be adjusted if the care team feels that is appropriate for a given beneficiary population. As it may be a challenge for some EOM participants to increase staffing or adjust roles to support ePROs data collection and follow-up based on notifications, we encourage EOM participants to be proactive in developing staffing and workflow strategies related to ePROs during the planning years (model years 1 and 2).

EOM participants may experience an increase in message volume and alert notifications, including other communications like portal messages and voicemails. EOM participants should prepare to assess how much time is needed for staff and care team members to address alert notifications and evaluate whether additional staff, support, and/or other personnel are needed to meet the needs of beneficiaries. Suggested workflow changes that may help participants manage staffing requirements to support ePROs data collection and follow-up include:

- Creating thresholds for symptom reports (e.g., monitoring symptom reports over time and adjusting alert thresholds based on collected beneficiary-level data);
- Asking beneficiaries whether these symptoms can be addressed at scheduled clinic visits; and
- Digital healthcare investments to accommodate a higher volume of communication between EOM beneficiary and participant (e.g., an updated portal, omnichannel communication, or artificial intelligence-enabled triage enhancements).

EOM participants should train staff to follow up with eligible beneficiaries who do not engage with the ePROs surveys and/or whose engagement is delayed. Staff are expected to reach out to beneficiaries to inquire into their reason for not responding, as a non-response could indicate other potential concerns. Preparing follow-up scripts may help standardize this process.

2.5 Engaging Beneficiaries and Equity among Beneficiary Populations

EOM beneficiaries should not be expected to participate in ePROs data collection without being provided adequate information about its value to them and their care team. Beneficiaries should understand that ePROs monitoring is a standard part of how their care is delivered. They should also understand the rationale behind their oncologist's and other care team members' desire for them to use it, and how their participation can lead to proactive/earlier symptom management.

A potential risk to equitable implementation, access, and use of ePROs is varying experience levels with technology among beneficiary populations. For example, beneficiaries with limited prior technology experience (e.g., lack of broadband or smart devices), those with limited data plans, or those with different communication preferences may not reap the full benefits of ePROs monitoring if the care team cannot adequately engage with beneficiaries.[54] EOM participants are encouraged to meet the needs of their unique beneficiary population; these efforts may include finding alternative ways to collect and monitor beneficiary ePROs (e.g., automated phone calls, or an in-clinic solution such as staff administered surveys).

Beneficiaries' participation in ePROs reporting will be increased if they are offered a choice of interfaces (e.g., web, smart device, or automated telephone system, with options for prompts by e-mail, text, or automated phone call).

All beneficiaries should be informed about the ePROs monitoring system, regardless of their assumed experience with technology. Beneficiaries with limited prior computer experience have been found to engage highly successfully with ePROs data collection surveys and software and in fact yield greater benefits from ePROs than more technically advanced beneficiaries, likely because of baseline communication barriers that the ePROs software can transcend.[55] Beyond the mode of administration, there may be language preferences or other ways of communicating and discussing ePROs depending on the patient population that need to be considered.

2.6 Organizational Commitment and Sustainability

In any form of care enhancement, implementation can bring changes in workflow, information flow, deployment, and culture. It's important for EOM participants to have commitment from organizational leadership with messaging across staff and clinicians that program success is a priority for successful ePROs adoption and implementation.

Engagement of leaders and staff can be enhanced by providing information on the clinical benefits of ePROs monitoring for quality of care, patient centeredness, and other benefits such as increased adherence to treatment regimens as well as reduced hospitalizations and ED visits. Care team leaders should play a role in orienting staff to ePROs data collection goals and timelines, mapping processes, engaging with frequent updates and communication; and tracking specific metrics to ensure ePROs data collection is robust and complete.

Prior ePRO implementations have used key metrics to monitor ePRO data as it is received. Some specific metrics to continuously collect are included in Table 2:[56]

Table 2. Beneficiary Engagement Metrics

Metric	Target Engagement
Proportion of beneficiaries that are offered participation with PRO self-reporting	100% of eligible beneficiaries should be offered participation
Proportion of beneficiaries that agree to participate	A target of 65 to 80 percent of eligible beneficiaries should participate
Proportion of participating beneficiaries who provide ePROs data at least once.	A target of 80 to 90 percent is reasonable in medical oncology.
Proportion of participating beneficiaries that comply with PRO self-reporting at expected time points (e.g., before each E&M visit)	A target of 60 to 80 percent of participating eligible beneficiaries should comply
Proportion of PRO alert notifications with a navigator and nurse response/outreach	At target of 55 to 75 percent of PRO alert notifications should receive a response from navigators and nurses, as clinically appropriate.

Additional key metrics to continuously collect include:

- Prevalence of each symptom across the beneficiary population.
- Number of providers and staff trained on PRO systems
- All patients are trained to use the PRO system
- Number of alert notifications generated
- Care team members' time to providing responses to alert notifications and alert closure.
    - Potential care team responses to alerts include: a telephone call to counsel the beneficiary; prescription of a supportive medication; a new appointment; referral to urgent care/emergency room (ER); or no action necessary (symptom already addressed; can wait for next visit).
    - A documented response should always be recorded.
    - Timeliness of response (e.g., responding to beneficiaries within one business day, as is clinically appropriate)

The engagement metrics listed above are example metrics for EOM participants' internal tracking. We encourage EOM participants to tailor and track metrics that make sense for your practice and beneficiary needs.

EOM participants should be committed to engaging beneficiaries in ePROs reporting. Engagement should be monitored from the initial outreach. ePROs engagement with beneficiaries is a spectrum and may differ across different points. For example, four key points of along the engagement timeline include:

1) Initial outreach: when initially communicating with beneficiaries about ePROs, it is key to explain that ePROs are a part of routine care delivery and that they will be used to inform and improve care and care outcomes as well as enable the best possible beneficiary experience. It

should be explained that providers will be reviewing the beneficiary's reported information, however, it should not be relied upon as the sole method for communicating symptoms. ePROs should be offered to all EOM eligible beneficiaries, but some beneficiaries may choose to not use ePROs or decline ePROs survey administration e.g., for example, some patients may signal they can wait until the next visit. EOM participants should follow up with beneficiaries who choose to initially not use ePROs reporting as beneficiary needs and interest in ePROs may shift over time and over course of treatment. We encourage EOM participants to follow up with beneficiaries who do not choose to report via ePROs as this may signal other concerns (e.g., lack of awareness of ePROs or their potential benefit as part of care, barriers in access to or various levels of comfort with technology or broadband, comfort in sharing information with the clinical team, etc.).

2) ePROs Reporting: for beneficiaries who submit ePROs, a brief training session or video should be provided on the key functionalities of the software and practice workflow for ePROs as well their potential benefit and how they will be used to inform care. Contact information should be provided for any questions or difficulties that beneficiaries may have.

3) Clinical follow up to reported ePROs: all real time alert notifications triggered by the ePROs system should be reviewed by a clinical team member within 1 business day. There should be documentation of either outreach and/or clinical action taken in response to the alert notification, if warranted, or that no outreach/action was needed. Longitudinal reports of symptoms should be reviewed by team members at visits and reviewed with patients as warranted.

4) Monitoring over time: EOM participants should be deliberate in care redesign as they navigate how to manage the heightened awareness of symptoms across their beneficiaries that results from ePROs data collection. Longitudinal data can be used both at the beneficiary level for understanding trends, and at the practice level for identifying quality improvement activities, for example, related to pain management, or symptom control more broadly during treatment. Proactive symptom monitoring will likely reveal issues previously unaddressed in beneficiaries that now need to be addressed. EOM participants should consider directing beneficiaries with newly identified symptoms to supportive care programs such as palliative care or behavioral health, and to support groups and family learning resources. Other care transformation activities to help EOM participants manage more beneficiaries with identified needs include increasing the pool or use of navigators, social workers, clinical pharmacists, counselors, community health workers, home health services, and/or palliative care providers.

In addition to implementing ePROs data collection, the EOM participant should commit to regularly reviewing the processes and procedures for ePROs data collection. There are often initial challenges with care team acceptance (resistance to the idea because of the additional or altered workflow) and a slow start to beneficiary participation and engagement. It is important to recognize these challenges and identify process improvement opportunities through deep dives into barriers or staff concerns to improve and optimize engagement. Regularly reviewing and updating ePROs data collection processes and procedures is one way that EOM participants can

meet the PRA requirement of utilizing data for continuous quality improvement. Continuous messaging should emphasize the importance of ePROs data collection.

Additionally, when HRSNs such as transportation concerns, food insecurity, or housing instability are identified, beneficiary access to financial counselors, social workers, and/or community health workers may improve care and access. More information on HRSN screening can be found on the EOM website in the EOM Health-Related Social Needs Guide.

Section 3: Additional EOM Resources

CMS EOM Website

- https://innovation.cms.gov/innovation-models/enhancing-oncology-model

EOM Connect:

- https://app.innovation.cms.gov/CMMIConnect/IDMLogin

EOM Support:

- EOMSupport@cms.hhs.gov
- 1-844-734-6433 option 3

Appendix A: Key Terms Used in this Guide

Term	Definition
PRO	Patient Reported Outcomes (PROs) are measurements based on a report that comes directly from the patient, without amendment or interpretation of the patient's response.[57] ePROs are the electronic capture of this data. [58]
ePRO (singular version)	One electronic patient reported outcome (PRO)
ePROs (plural version)	Multiple electronic patient-reported outcomes (PROs)
ePROs software	The technical system for administering ePROs surveys to patients.
Domains	The "outcomes" in ePROs, e.g., pain or physical function.
Instruments or Tools	The actual "questionnaires" developed scientifically that contain "items" or "questions" that represent the outcome.
Surveys	The groups of items/questions assembled for administering ePROs surveys to patients.
Items	Questions that represent the outcome, included on the "instruments," "tools," and "surveys."

Appendix B: Additional Key Terms Related to ePROs Collection and Implementation

Term	Working Definition	Additional Context
Remote symptom monitoring	Use of connected health technologies to systematically collect patient-reported symptoms and convey this information to care team members via alert notifications and reports	https://ascopubs.org/doi/full/10.1200/CCI.22.00187
Remote therapeutic monitoring	Use of connected health technologies for remote managing and collection of non-physiological patient data, with specific definitions and parameters defined by current CPT codes 98975, 98976, 98977, 98980, 98981.	https://www.cms.gov/files/document/mm12446-2022-annual-update-therapy-code-list.pdf
Remote patient monitoring	Use of connected health technologies for remote managing and collection of physiological patient data, with specific definitions and parameters defined by current CPT codes 99453, 99454, 99457, 99458, 99091.	https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1
Software as a medical device	Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device	https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

Appendix C: Checklist: Preparing for ePROs Implementation

EOM participants who so choose will begin implementation in Model Years 1&2. All EOM participants will be required to develop the capabilities necessary to successfully implement ePROs in a manner consistent with the standard domains and implementation requirements by Model Year 3. This checklist is designed to support participants' successful ePROs planning and implementation. We acknowledge that participants will be at different stages of ePROs implementation, and some of these questions may not apply to all participants. Resources to assist participants are provided at the end of the checklist and included throughout this guide.

Preparing for EPROS Implementation

Preparing for EPROS Implementation

This checklist is intended to be used as a resource to support Enhancing Oncology Model (EOM) participants during the pre-implementation period of electronic patient-reported outcomes (ePROs) data collection. We acknowledge that participants will be at different stages of ePROs implementation, and some of these questions may not apply to all participants. This checklist is for your own use and does not need to be submitted to CMS. The overall goal is to support successful implementation. Resources to assist you are provided at the end of this checklist.

1. **My EOM PGP already collects PROs using surveys in any patient population at my practice.**

- ◯ No
- ◯ Yes

My PGP uses _____

1a. If yes, my PGP collects PROs either electronically or via paper.

- ◯ Electronic
- ◯ Paper

1b. If electronic, my EOM PGP collects ePROs via our EMR system or a third-party vendor.

- ◯ Part of EMR system
- ◯ Third-party vendor

2. **My EOM PGP already collects PROs, for example symptoms or distress. My PGP has developed alert notifications to get triggered by the PRO system.**

- ◯ No
- ◯ Yes

2a. If yes, this occurs in the following way: (Describe)

2b. If no, are you considering starting? (Please provide details)

(If your EOM PGP has already implemented ePROs, you may want to stop the checklist here.)

Getting Started

1. My EOM PGP has accessed and begun to review the surveys suggested in the ePROs Guide.

- ◯ No
- ◯ Yes

Preparing for EPROS Implementation

2. My EOM PGP has already decided on a particular survey to use for our beneficiaries.

- ◯ No
- ◯ Yes

My PGP has decided to use _____

3. My EOM PGP has already contacted IT vendors to begin preparing for ePROs implementation.

- ◯ No, we have not yet contacted vendors to begin preparing for ePROs implementation.
- ◯ Yes

Which IT vendor? _____

4. Does your EOM PGP foresee future challenges or barriers with implementation of ePROs in your practice?

- ◯ No
- ◯ Yes

How will your practice address/mitigate these challenges or barriers?

Clear Form Print 3

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