EOM ELECTRONIC PATIENT REPORTED OUTCOMES GUIDE

Version 1.0

June 20, 2023

Prepared by:
Centers for Medicare & Medicaid Services
Center for Medicare & Medicaid Innovation

Revision History

Revision #	Revision Date	Description of Change
1.0	6/20/23	– Initial Version

Table of Contents

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 EOM Enhanced Services as part of EOM 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 chemotherapy. 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 chemotherapy for cancer and the model is centered on 6-month episodes of care triggered by receipt of chemotherapy. Seven cancer types are included in the model:

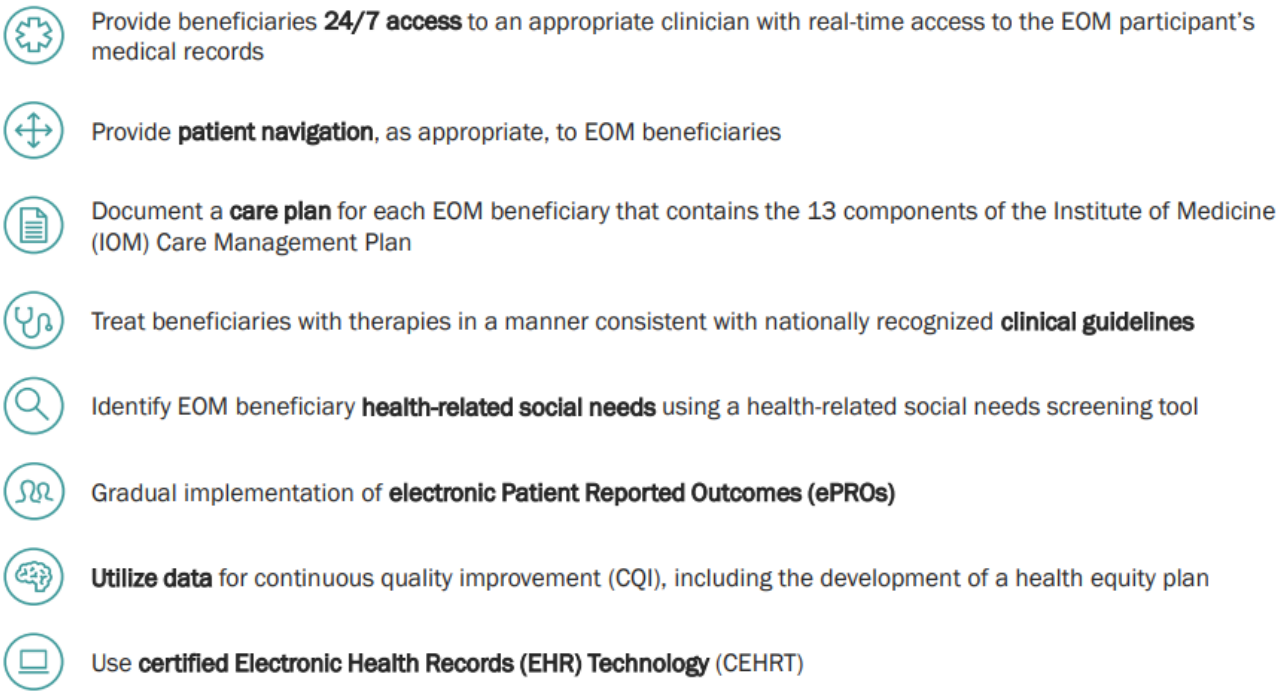
1. breast cancer [a]
2. chronic leukemia
3. lung cancer
4. lymphoma
5. multiple myeloma
6. prostate cancer [a]
7. small intestine / colorectal cancer

In alignment with the Centers for Medicare & Medicaid Services' (CMS's) 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]

EOM participants are required to implement eight Enhanced Services as part of their participant redesign activities (PRAs) (**Figure 1**). In alignment with CMS's commitment to focusing on whole-person care, EOM is designed with patient-centeredness at the forefront. To that end, one Enhanced Service required of EOM participants *is gradual implementation of collecting electronic patient-reported outcomes (ePROs) for eligible EOM beneficiaries*.

[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.

Figure 1. EOM Participant Redesign Activities



The collection and use 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.[9,10,11,12,13,14,15,16]

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.[17,18,19] 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.[20,21,22,23]

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

Because there are many ePROs surveys available, CMS does not 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 that may already be in use by EOM participants prior to EOM start.

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

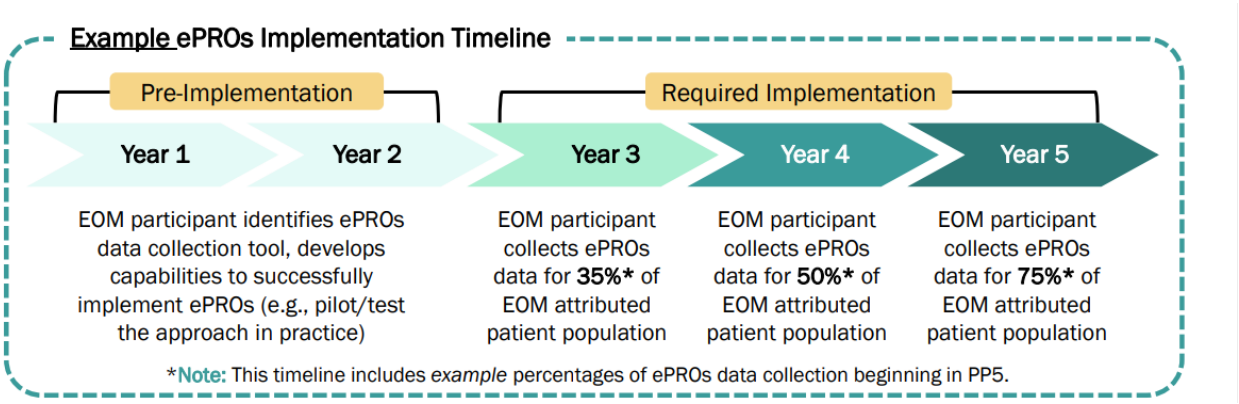
- *Symptoms and/or symptomatic toxicities*
  - Individual evaluation of symptoms that are common across cancer types, for example: anorexia (appetite loss/decreased oral intake), constipation, diarrhea, dyspnea, mucositis, nausea, pain, sensory neuropathy, vomiting.[24]
- *Functioning*
  - Physical functioning, 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 toxicity, transportation insecurity, food insecurity, housing insecurity

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 or governmental 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.

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 a percentage of beneficiaries that increases each model year, beginning with model year 3 (e.g., 35 percent, 50 percent, 75 percent). EOM participants will engage with patients through gradual implementation of ePROs to better identify patients' needs, improve patient-provider communication, care management, patient satisfaction, and advances in 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 engagement, 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 for visualizing ePROs data in the EMR, identifying eligible patients for ePROs participation, documentation, 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 better 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.[25,26]

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 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 noted in PA Article VII, Section 7.2. Should an EOM participant be selected for a monitoring site visit, the participant will be required 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 dependent on beneficiary need. Some past ePROs programs and research have demonstrated the benefits of beneficiaries completing ePROs surveys on a regular scheduled basis, for example weekly from home.[27,28]

In addition to the gradual implementation of ePROs, another PRA requirement is the use of established, validated screening tools to collect HRSN data from EOM beneficiaries and to develop a plan for addressing those needs. EOM participants are required to use ePROs survey(s) that capture, where applicable, beneficiary-level outcomes for four required domains, one of which is health related social needs (HRSN). For HRSN requirements, 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 every 6 months and still field screening questions every E&M visit to check in with beneficiaries for updates or changes.

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 set up ePROs with the EOM beneficiary. The ePROs 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 PROs, because this approach will require subsequent manual data entry and can introduce errors. Additionally, compliance cannot be monitored easily or in real-time. However, paper can be considered as a backup data collection approach for patients unable to report other ways.

To reduce EOM beneficiary burden, ePROs assessment duration for patients should be brief, for example no longer than a few 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.[29] Successful implementation of ePROs data collection helps ensure the full benefits of a symptom monitoring program are felt by the patient 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
  - Capability 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 full ePROs report, 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's 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 PRO 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)[30]

- Patient-Reported Outcomes Measurement Information System (PROMIS)[31]
- Edmonton Symptom Assessment Scale (ESAS)[32]
- MD Anderson Symptom Inventory (MDASI)[33]
- European Organization for Research and Treatment of Cancer (EORTC) Quality of Life (QOL) item library[34]
- Patient Health Questionnaire-2 (PHQ-2) 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)
- ESMO Clinical Practice Guidelines

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[35]
- Comprehensive Geriatric Assessment Form[36]
- PROMIS Global-06 item from PROMIS global items[37]

2.3 ePROs Alert Notifications

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

- Setting an absolute level threshold 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;
- 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.

Strategies to reduce the number of triggered notifications include assessing whether the patient's need can be addressed without needing an office visit, enabling clinicians to selectively turn off or pause 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.

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 practices 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).

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 equity for ePROs implementation is varying experience levels with technology among beneficiary populations. For example, beneficiaries with limited prior technology experience (i.e., 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.

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.[38]

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 ePROs implementations have used key metrics to monitor ePRO data as it is received. Some specific metrics to continuously collect include:[39]

- Proportion of eligible beneficiaries who are identified and invited to provide ePROs data.
    - All or most eligible beneficiaries should be invited.
- Proportion of invited beneficiaries who agree to participate.
    - A target of 65 to 80 percent is reasonable in medical oncology.
- 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 who self-report ePROs before each E&M visit.
    - A target of 60 to 80 percent average adherence is reasonable in medical oncology.
- Prevalence of each symptom across the beneficiary population.
- 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/ER; or no action necessary [symptom already addressed; can wait for next visit]).
    - A documented response should always be recorded.

In addition to implementing ePROs data collection, the EOM participant should commit to regularly reviewing the processes and procedures of the ePROs data collection efforts. 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.

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. Proactive symptom monitoring will likely reveal issues previously unaddressed in beneficiaries that now must 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.

Additionally, when health-related social needs (HRSN) are identified such as financial toxicity, transportation insecurity, food insecurity, or housing insecurity, 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/EOMConnect

EOM Support:

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

Appendix A: Key Terms Used in this Guide

Term	Definition
ePRO (singular version)	One electronic patient reported outcome
ePROs (plural version)	Multiple electronic patient-reported outcomes
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."

References

[1] Brooks-LaSure, C., Fowler, E., Seshamani, M. & Tsai, D. (2021). Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years. Health Affairs.

[2] Centers for Medicare & Medicaid Services, Office of Minority Health (2021). Paving the Way to Equity: A Progress Report.

[3] American Association for Cancer Research, "AACR Cancer Disparities Progress Report 2020."

[4] Jemal, A., Siegal, R.L., Ma, J., Islami, F., DeSantis, C., Sauer, A.G., Simard, E.P., Ward, E.M. (2015). Inequalities in Premature Death from Colorectal Cancer by State. Journal of Clinical Oncology.

[5] Green, A.K., Aviki, E.M., Matsoukas, K., Patil, S., Korenstein, D., & Blinder, V. (2018). Racial disparities in chemotherapy administration for early-stage breast cancer: a systematic review and meta-analysis. Breast Cancer Research and Treatment.

[6]Smith., A.K., Earle, C.C., & McCarthy, E.P. (2008). Racial and Ethnic Differences in End-of-Life Care in Fee-for-Service Medicare Beneficiaries with Advanced Cancer. Journal of the American Geriatrics Society.

[7] Ajewole, V.B. et al., (2021). Cancer disparities and black American representation in clinical trials leading to the approval of oral chemotherapy drugs in the United States between 2009 to 2019. JCO Oncology Practice.

[8] AACR Cancer Disparities Progress Report. (2020). American Association for Cancer Research.

[9] Basch E, Deal, A.M, Dueck, A.C, et al. (2017) Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA. 318(2):197–198.

[10] Ladanie, A., Schmitt, A.M., Speich, B. (2020). Clinical trial evidence supporting US Food and Drug Administration approval of novel cancer therapies between 2000 and 2016. JAMA.

[11] Denis, F., Basch, E., Septans, A.L., Bennouna, J., Urban, T., Dueck, A.C., Letellier, C. Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer. JAMA. 2019 Jan 22;321(3):306-307.

[12] Barbera, L, Sutradhar, R., Seow, H., Mittmann, N., Howell, D., Earle, C.C., Li, Q, Thiruchelvam, D. The impact of routine Edmonton Symptom Assessment System (ESAS) use on overall survival in cancer patients: Results of a population-based retrospective matched cohort analysis. Cancer Med. 2020 Aug 14;9(19):7107–15.

[13] Chen, J., Ou, L., & Hollis, S.J. (2013). A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organizations in an oncologic setting.

[14]Basch, E., Deal, A.M., Kris, M.G., Scher, H.L., Hudis, C.A., Sabbatini, P., Rogak, L., Bennett, A.V., Dueck, A. C., Atkinson,T.M., Chou, J.F., Dulko, D., Sit, L., Barx, A., Novotny, P., Fruscione, M., Sloan, J.A. & Schrag, D. (2016). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. J Clin Oncol. 2016 Feb 20;34(6):557-65.

[15] Barbera, L., Sutradhar, R., Seow, H., Earle, C.C., Howell, D., Mittmann, N., Li, Q., Thiruchelvam, D. Impact of Standardized Edmonton Symptom Assessment System Use on Emergency Department Visits and Hospitalization: Results of a Population-Based Retrospective Matched Cohort Analysis. JCO Oncol Pract. 2020 Sep;16(9):e958-e965.

[16] Mir, O., Ferrua, M., Fourcade, A., Mathivon, D., Duflot-Boukobza, A., Dumon, S, Baudin, E., Delaloge, S., Malka, D., Albiges L., Pautier, P., Robert, C., Planchard, D., de Botton, S., Scotté, F., Lemare, F., Abbas, M.,

Guillet, M., Puglisi, V., Di Palma, M., Minvielle, E. Digital remote monitoring plus usual care versus usual care in patients treated with oral anticancer agents: the randomized phase 3 CAPRI trial. Nat Med. 2022 Jun; 28(6): 1224-1231.

[17] Basch E., Deal A.M., Dueck A.C., et al. (2017) Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring during Routine Cancer Treatment. JAMA. 318(2):197-198.

[18]Denis, F., Basch, E., Septans, A.L., et al. (2019) Two-Year Survival Comparing Web-Based Symptom monitoring vs Routine Surveillance Following Treatment for Lung Cancer. JAMA. 321(3) 306-307.

[19] Ladanie, A., Schmitt, A.M., Speich, B. (2020). Clinical trial evidence supporting US Food and Drug Administration approval of novel cancer therapies between 2000 and 2016. *JAMA*. Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7656288/

[20]H.R. 6074 –Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020.

[21]Telehealth: Delivering Care Safely During COVID-19; retrieved from: https://www.hhs.gov/coronavirus/telehealth/index.html

[22]Verma, S. (2020). Early Impact of CMS Expansion of Medicare Telehealth During COVID-19. Health Affairs.

[23] Marandino, L., Necchi, A., Aglietta, M., & Di Maio, M. (2020). COVID-19 Emergency and the Need to Speed Up Adoption of Electronic Patient-Reported Outcomes in Cancer Clinical Practice. JCO oncology practice, 16(6), 295–298.

[24] Reilly, C.M., Bruner, D.W., Mitchell, S.A., Minasian, L.M., Basch, E., Dueck, A.C., Cella, D., Reeve, B.B. A literature synthesis of symptom prevalence and severity in persons receiving active cancer treatment. Support Care Cancer. 2013 Jun;21(6):1525-50.

[25] Wagner, L.I., Schink, J., Bass, M., Patel, S., Diaz, M.V., Rothrock, N., Pearman, T., Gershon, R., Penedo, F.J., Rosen, S., Cella, D. (2015). Bringing PROMIS to Practice: Brief and Precise Symptom Screening in Ambulatory Cancer Care. Cancer.

[26]Chung, A.E. & Basch, E.M. (2015). Incorporating the Patient's Voice into Electronic Health Records through Patient-Reported Outcomes as the "Review of Systems." Journal of the American Medical Informatics Association.

[27] Basch, E., Rocque, G., Mody, G., Mullangi, S., Patt, D. Tenets for Implementing Electronic Patient-Reported Outcomes for Remote Symptom Monitoring During Cancer Treatment. JCO Clin Cancer Inform. 2023 Feb;7:e2200187.

[28] Di Maio, M., Basch, E., Denis, F., Fallowfield, L.J., Ganz, P.A., Howell, D., Kowalski, C., Perrone, F., Stover, A.M., Sundaresan, P., Warrington, L., Zhang, L., Apostolidis, K., Freeman-Daily, J., Ripamonti, C.I., Santini, D. ESMO Guidelines Committee. Electronic address: clinicalguidelines@esmo.org. The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline. Ann Oncol. 2022 Sep;33(9):878-892.

[29] See Reference 27.

[30] The PRO-CTCAE Measurement System (https://healthcaredelivery.cancer.gov/pro-ctcae/)

[31] PROMIS (healthmeasures.net)

[32] What is the Edmonton Symptom Assessment Scale (ESAS)? (qdhpca.org).

[33] MD Anderson Symptom Inventory (MDASI) | MD Anderson Cancer Center.

[34] EORTC Quality of Life Website - EORTC - Quality of Life : EORTC – Quality of Life.

[35] Al-Rashdan, A, Sutradhar, R., Nazeri-Rad, N., Yao, C, Barbera, L. Comparing the Ability of Physician-Reported Versus Patient-Reported Performance Status to Predict Survival in a Population-Based Cohort of Newly Diagnosed Cancer Patients. Clin Oncol (R Coll Radiol). 2021 Feb 3:S0936-6555(21)00008-X.

[36] Capital Health Comprehensive Geriatric Assessment Form; retrieved from https://cdn.dal.ca/content/dam/dalhousie/pdf/sites/gmr/OurTools_CGA.pdf

[37] See Reference 31.

[38] See Reference 27.

[39] See Reference 27.