RO Model Quality Measure and Clinical Data Element Collection and Submission Guide

Version 1.0

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CONTENTS

1. Introduction

The Radiation Oncology (RO) Model is an innovative payment and service delivery model designed to preserve or enhance the quality of care furnished to beneficiaries who are receiving radiotherapy (RT) services while reducing program spending through enhanced financial accountability for model participants. The RO Model's design seeks to provide more predictable payments for participating providers and suppliers. The Center for Medicare and Medicaid Innovation (Innovation Center) of the Centers for Medicare & Medicaid Services (CMS) will use the RO Model to test whether site-neutral, prospective, episode-based payments made to physician group practices (PGP), freestanding radiation therapy centers, and hospital outpatient departments (HOPDs) for certain RT services furnished during a 90-day RO episode for included cancer types for certain Medicare beneficiaries will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. The model performance period consists of five performance years.[1] More details about the RO Model can be found at https://innovation.cms.gov/innovation-models/radiation-oncology-model.

The RO Model Quality Measure and Clinical Data Element Collection and Submission Guide (the guide) for RO participants describes the RO Model's data reporting requirements.

This guide is one of several resources for RO participants. CDE templates can be downloaded from the RO Model Secure Data Portal.

The guide is organized into four sections:

- **Section 2** provides definitions of key terms such as RO participant, RO beneficiary, and RO episode.
- **Section 3** describes the Clinical Data Elements (CDEs) that RO participants must report.
- **Section 4** discusses the required quality measures (QMs).
- **Section 5** discusses the Aggregate Quality Score (AQS) methodology.

Written feedback on the contents of this document can be sent via email to RadiationTherapy@cms.hhs.gov. Please include "QM/CDE Guide Feedback" in the subject line of the email. Comments are due by August 13, 2021.

[1] Finalization of the RO Model start date and performance years is pending.

2. Key Terms and Definitions

Throughout this guide, we refer to the RO Model, RO participants, RO beneficiaries, RO episodes, CDEs and quality measures, Consumer Assessment of Healthcare Providers and Systems (CAHPS®), reporting intervals, AQS, and portals. To help readers better understand the guide, we define these terms below.[2]

- The **RO Model** is a mandatory prospective episode-based payment model.
- An **RO participant** is a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model in accordance with 42 CFR 512.210. There are three types of RO participants:
    - A **Professional participant** is a Medicare-enrolled PGP, identified by a single tax identification number (TIN), that furnishes only the professional component of an RO episode.
    - A **Dual participant** furnishes both the professional and technical components of RT services of an RO episode through a freestanding radiation therapy center, identified by a single TIN.
    - A **Technical participant** is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS certification number (CCN) or TIN, which furnishes only the technical component of an RO episode.
- **RO beneficiary** means a Medicare beneficiary who meets all of the beneficiary inclusion criteria at 42 CFR 512.215(a) and whose RO episode meets all the criteria defined at 42 CFR 512.245.
    - An individual is an **RO beneficiary** if:
        - The individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the RO Model performance period for an included cancer type; and
        - At the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual:
            - Is eligible for Medicare Part A and enrolled in Medicare Part B,
            - Has traditional fee-for-service Medicare as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance), and
            - Is not in a Medicare hospice benefit period.
    - Any individual enrolled in a clinical trial for RT services for which Medicare pays routine costs is an RO beneficiary if the individual satisfies all of the beneficiary inclusion criteria (see above).

[2] 42 CFR § 512.205 – Definitions.

- An **RO episode** is the 90-day period that, as set forth in 42 CFR 512.245, begins on the date of service that a Professional participant or Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service.
- **CDEs** are key pieces of information about the RO beneficiary's care that are not available through typical reporting mechanisms such as Medicare claims data or quality measure reporting. CDEs provide information about cancer stage and histology, the RO beneficiary's performance status, and the intent of treatment.[3]

Professional participants and Dual participants are required to report CDEs and quality measures.

- **Quality measures (QMs)** are tools that help measure or quantify health care processes, outcomes, patient perceptions, and organizational structures or systems (1) associated with the provision of high-quality health care or (2) related to one or more quality goals for health care. Quality measures can identify important aspects of care such as safety, effectiveness, timeliness, and fairness.[4]
- **The CAHPS® Cancer Care Survey – Radiation Therapy** assesses the experiences of adult patients receiving cancer treatment in outpatient and inpatient settings (the RO Model focuses on the outpatient setting). The survey results will contribute to the AQS for all RO participants beginning in Performance Year (PY) 3.

CDEs, quality measure data, and CAHPS® Cancer Care Survey results will help RO participants improve the patient-centeredness of cancer care.

- **Reporting periods**
    - **CDEs** are reported biannually at the RO beneficiary level—by July 31 for RO episodes ending between January 1 and June 30 and by January 31 for RO episodes ending between July 1 and December 31.
    - **Quality measure data** are reported at the TIN-NPI level, annually for all patients receiving RT services from Professional participants and Dual participants in the preceding calendar year, January 1 through December 31. Reporting is due by March 31 of the following calendar year.

[3] There are three administrative data elements (RO Model ID and RO beneficiary, Medicare Beneficiary Identifier (MBI), and date of birth) that are reported, along with the CDEs. For clarity and ease of reading, we use "CDE" to refer, collectively, to both administrative and clinical data.
[4] CMS. "What Is a Quality Measure?" Last modified March 2021. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/NTM-What-is-a-Quality-Measure-SubPage. Accessed April 5, 2021.

- The **AQS** is the numeric score calculated for each RO participant based on its performance on, and reporting of, applicable quality measures, and CDEs. The AQS is used to determine an RO participant's quality reconciliation payment amount. CAHPS® scores will be added to the AQS starting in PY3.
- The **RO Secure Data Portal** is the mechanism used by RO participants to download blank CDE templates, upload populated CDE templates, and input aggregate quality measure data directly.

3. Clinical Data Elements

Professional participants and Dual participants must submit CDEs for RO beneficiaries treated with an included RT service for five included cancer types: (1) prostate, (2) breast, (3) lung, (4) bone metastases, and (5) brain metastases. Table 1 shows the data elements required for reporting.

This section describes the CDEs that Professional participants and Dual participants must report for RO beneficiaries who completed their RO episode during the reporting period.

Table 1. Required clinical data elements

	Breast	Prostate	Lung	Bone metastases	Brain metastases
RO Model identifier	✓	✓	✓	✓	✓
Medicare beneficiary identifier	✓	✓	✓	✓	✓
ECOG or KPS score	✓	✓	✓	✓	✓
AJCC TNM staging	✓	✓	✓		
Intent of treatment	✓	✓	✓		
Histology	✓		✓		
Laterality	✓				
ISUP Grade Group or Gleason score		✓			
Anatomic target[a]	✓	*(opt.)*	*(opt.)*		
Fractions[a]	✓	*(opt.)*	*(opt.)*		
Dose per fraction[a]	✓	*(opt.)*	*(opt.)*		
Total dose[a]	✓	*(opt.)*	*(opt.)*		
Prior RT to an overlapping area				✓	
Prior RT to brain					✓

[a] RO participants must report anatomic target, dosage, and fraction data for RO beneficiaries treated for breast cancer. Reporting of this information is optional for prostate and lung cancer.

ECOG = Eastern Cooperative Oncology Group; KPS = Karnofsky Performance Score; AJCC TNM = American Joint Committee on Cancer tumor node metastasis; ISUP = International Society of Urological Pathology.

If an RO beneficiary has multiple primary cancers, CDEs will be reported for the cancer type billed by the RO participant for the RO beneficiary's episode.

3.1 Clinical Data Elements Common Across Include Cancer Types

Six CDEs are common across the five included cancer types (prostate, breast, and lung cancers, and bone and brain metastases)—RO Model ID, Medicare Beneficiary Identifier (MBI), performance status, dosage, and fractions.

3.1.1 RO Model identification (ID) number

Variable name: rom_id	
Description:	RO Model participant identification (ID) number
Format:	Alphanumeric
Length:	8
Example:	ROM-####
Instructions:	Record the RO Model participant ID corresponding to the Professional participant or Dual participant who furnished services to the RO beneficiary. If data are being reported for multiple Professional participants or Dual participants, upload one Microsoft® Excel spreadsheet per cancer type per RO participant (see Sections 3.9 and 3.10).
Purpose:	Confirms that CMS associates RO participants with the correct CDE data

3.1.2 Medicare Beneficiary Identifier

Variable name: mbi	
Description:	Medicare Beneficiary Identifier
Format:	Standard Medicare Beneficiary Identifier format[5]
Length:	11
Example:	1A02A08AA09
Instructions:	Provide the Medicare Beneficiary Identifier for each RO beneficiary who completes an RO episode during the reporting period. CDEs are reported only for patients who meet the definition of an RO beneficiary.
Purpose:	Allows RO beneficiary CDE data to be linked with RO beneficiary Medicare claims data. In addition, if issues with data quality arise, the RO participant can determine which RO beneficiary records need to be accessed.

[5] CMS. "Understanding the Medicare Beneficiary Identifier (MBI) Format." n.d. Available at https://www.cms.gov/medicare/new-medicare-card/understanding-the-mbi-with-format.pdf. Accessed April 5, 2021.

3.1.3 Performance status

- Report either the Eastern Cooperative Oncology Group (ECOG) performance status score[6] or the Karnofsky Performance Score (KPS) score[7] for each RO beneficiary.
- If both scores are available for the RO beneficiary, report the one that is documented closest to the start of the RO episode, which could be before the start of the episode.
- If both scores are documented on the same date closest to the start of the RO episode, report the KPS score.

3.1.3.1 ECOG

Variable name: ecog

Description: ECOG performance status score
Format: Integer
Length: 1

Valid values:
0 = Fully active, able to carry on all pre-disease performance without restriction
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work)
2 = Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50 percent of waking hours
3 = Capable of only limited self-care; confined to bed or chair more than 50 percent of waking hours
4 = Completely disabled; cannot carry on any self-care; totally confined to bed or chair
5 = Dead

[6] ECOG-ACRIN Cancer Research Group. "ECOG Performance Status." n.d. Available at https://ecog-acrin.org/resources/ecog-performance-status. Accessed March 22, 2021
[7] National Palliative Care Research Center. "Karnofsky Performance Status Scale Definitions Rating (%) Criteria." n.d. Available at http://www.npcrc.org/files/news/karnofsky_performance_scale.pdf. Accessed March 22, 2021.

3.1.3.2 KPS

Variable name: kps

Description: KPS score
Format: Integer
Min. length: 1
Max. length: 3

Valid values:
100 = Normal; no complaints; no evidence of disease
90 = Able to carry on normal activity; minor signs or symptoms of disease
80 = Normal activity with effort; some signs or symptoms of disease
70 = Cares for self; unable to carry on normal activity or do active work
60 = Requires occasional assistance but is able to care for most needs
50 = Requires considerable assistance and frequent medical care
40 = Disabled; requires special care and assistance
30 = Severely disabled; hospitalization is indicated, although death not imminent
20 = Very sick; hospitalization necessary; active supportive treatment necessary
10 = Moribund; fatal processes progressing rapidly
0 = Dead

3.2 Phases and Anatomic Target, Dosage, and Fractions[8]

- Reporting anatomic target(s), dosage(s), and fraction(s) for all RO beneficiaries treated for **breast cancer is mandatory**.
- Reporting anatomic target(s), dosage(s), and fractions for all RO beneficiaries treated for **prostate cancer or lung cancer is optional**.
- The RO Model is collecting target, dosage, and fraction data in the same manner as required for facilities accredited by the Commission on Cancer (CoC).

Why are RO participants reporting detailed dosage and fractions data only for RO beneficiaries treated for breast cancer? *To obtain high-quality data that can be used for future quality measurement, the RO Model team opted (in PY1) to require data for one cancer type only to allow RO participants to build this capacity. These data may be required for other cancer types in the future.*

[8] Information about reporting anatomic target, dose, and fractions is taken from two freely available resources: the Standard for Oncology Registry Entry (STORE) 2021 and the CTR Guide to Coding Radiation Therapy Treatment in the STORE (V3.0). In some instances, information is taken verbatim, for consistency between the RO Model Quality Measure and Clinical Data Element Collection and Submission Guide and STORE 2021.

Phases

- **Reporting of anatomic target, dosage, and fractions will be done for up to three phases of RT.** This terminology, adopted by the CoC, state registries and the National Cancer Institute, replaces the terms “regional” and “boost.”
- A course of RT consists of one or more phases and each phase **represents the RT prescription that was actually delivered.** Physicians write RT prescriptions addressing anatomic target(s) and specify the dose per fraction (session), the number of fractions, and other elements of treatment (e.g., modality, planning technique).
- The first phase (Phase I) of RT may be referred to as an initial plan and a subsequent phase (Phase II, III) may be referred to as a boost or cone down.
- Phases can be delivered sequentially or simultaneously. In sequential phases, a new phase begins when there is a change in the anatomic target volume of a body site, treatment fraction size, modality, or technique.
- Data are summarized from highest “Total Phase Dose” to lowest “Total Phase Dose” when multiple phases start on the same date. If multiple phases start on the same date and have the same Total Phase Dose, then any order is acceptable.
- Phase I must be coded; however, blanks will be allowed for Phase II and III if no radiation treatment is administered.

NOTE: Each of the anatomic target, node, fraction, and dose variables below are repeated for each phase. Phase I is denoted by “p1_” in front of the variable name. Phase II is denoted by “p2_” in front of the variable name. Phase III is denoted by “p3_” in front of the variable name.

3.2.1.1 Anatomic target

Variable name:	p1_anat, p2_anat, p3_anat
Description:	Primary anatomic target treated during Phase I-II-III of RT
Format:	Numeric
Length:	2
Valid values:	00-07, 09-14, 20-26, 29-32, 39-42, 50-68, 70-73, 80-86, 88, 90-93, 98-99
Example:	07
Instruction:	Indicate the primary anatomic target, which is typically the primary tumor or tumor bed. If the primary tumor or primary tumor bed was not targeted, record the other regional or distant site that was targeted. The p2_anat and p3_anat data fields should be left blank for RO beneficiaries receiving one phase of RT. The p3_anat data field should be left blank for RO beneficiaries receiving two phases of RT. Table 2 contains the anatomic targets, taken verbatim from the Standard for Oncology Registry Entry manual (STORE) 2021.

Table 2. Anatomic sites

Code	Label	Definition
00	No radiation treatment	Radiation therapy was not administered to the patient. Diagnosed at autopsy.
01	Neck lymph node regions	The primary treatment is directed at lymph node regions of the neck. Example situations include treatment of lymphoma or lymph node recurrence (in the absence of primary site failure) following definitive surgery of the primary tumor. If radiation to the neck lymph nodes includes the supraclavicular region, use code 03.
02	Thoracic lymph node regions	Radiation therapy is directed to some combination of hilar, mediastinal, and supraclavicular lymph nodes without concurrent treatment of a visceral organ site. Example situations include mantle or mini-mantle for lymphomas, and treatment of lymphatic recurrence after complete surgical excision of a thoracic primary. Note that the supraclavicular region may be part of a head and neck lymph node region. Use code 03 for treatments directed at neck nodes and supraclavicular nodes with a head and neck primary. Use code 04 if supraclavicular lymph nodes are part of breast treatment.
03	Neck and thoracic lymph node regions	Treatment is directed to lymph nodes in the neck and thoracic region without concurrent treatment of a primary visceral tumor. This code might apply to some mantle or mini-mantle fields used in lymphoma treatments or some treatments for lymphatic recurrences following definitive treatment for tumors of the head and neck or thoracic regions.
04	Breast/chest wall lymph node regions	Radiation is directed primarily to some combination of axillary, supraclavicular, and/or internal mammary lymph node sites WITHOUT concurrent treatment of the breast or chest wall. If the breast AND lymph nodes are being treated, then code the Primary Treatment Volume to Breast (codes 40 or 41) and Breast/Chest Wall Lymph Nodes (code 04) in Radiation to Draining Lymph Nodes.
05	Abdominal lymph nodes	Treatment is directed to some combination of the lymph nodes of the abdomen, including retrocrural, perigastric, perihepatic, portocaval and para-aortic nodes. Possible situations might include seminoma, lymphoma or lymph node recurrence following surgical resection of the prostate, bladder, or uterus.
06	Pelvic lymph nodes	Treatment is directed to some combination of the lymph nodes of the pelvis, including the common, internal and external iliac, obturator, inguinal and peri-rectal lymph nodes. This might be done for lymphoma or lymph node recurrence following definitive surgery for a pelvic organ.
07	Abdominal and pelvic lymph nodes	Treatment is directed to a combination of lymph nodes in both the abdomen and pelvis. This code includes extended fields (i.e., "hockey stick," "dog-leg," "inverted Y") utilized to treat seminomas and lymphomas or recurrence of a solid tumor.
09	Lymph node region, not otherwise specified (NOS)	This category should be used to code treatments directed at lymph node regions that are not adequately described by codes 01-07.
10	Eye/orbit/optic nerve	Treatment is directed at all or a portion of the eye, orbit and/or optic nerve.
11	Pituitary	Treatment is directed at the pituitary gland.

Code	Label	Definition
12	Brain	Treatment is directed at all the brain and its meninges (whole brain).
13	Brain (limited)	Treatment is directed at one or more sub-sites of the brain but not the whole brain. Chart may describe SRS, stereotactic radiosurgery, Gamma Knife.®
14	Spinal cord	Treatment is directed at all or a portion of the spinal cord or its meninges.
20	Nasopharynx	Treatment is directed at all or a portion of the nasopharynx.
21	Oral cavity	Treatment is directed at all or a portion of the oral cavity, including the lips, gingiva, alveolus, buccal mucosa, retromolar trigone, hard palate, floor of mouth and oral tongue.
22	Oropharynx	Treatment is directed at all or a portion of the oropharynx, including the soft palate, tonsils, base of tongue and pharyngeal wall.
23	Larynx (glottis) or hypopharynx	Treatment is directed at all or a portion of the larynx and/or hypopharynx.
24	Sinuses/nasal tract	Treatment is directed at all or a portion of the sinuses and nasal tract, including the frontal, ethmoid, sphenoid and maxillary sinuses.
25	Parotid or other salivary glands	Treatment is directed at the parotid or other salivary glands, including the submandibular, sublingual, and minor salivary glands.
26	Thyroid	Treatment is directed at all or a portion of the thyroid. Use code 98 when the thyroid is treated with I-131 radioisotope.
29	Head and neck (NOS)	The treatment volume is directed at a primary tumor of the head and neck, but the primary sub-site is not a head and neck organ identified by codes 20-26 or it is an unknown primary.
30	Lung or bronchus	Treatment is directed at all or a portion of the lung or bronchus.
31	Mesothelium	Treatment is directed to all or a portion of the mesothelium. This code should be used for mesothelioma primaries, even if a portion of the lung is included in the radiation field.
32	Thymus	Treatment is directed to all or a portion of the thymus.
39	Chest/lung (NOS)	Treatment is directed at a primary tumor of the chest, but the primary sub-site is unknown or not identified in codes 30-32. For example, this code should be used for sarcomas arising from the mediastinum.
40	Breast - whole	Treatment is directed at all the intact breast. Intact breast includes breast tissue that either was not surgically treated or received a lumpectomy or partial mastectomy.
41	Breast - partial	Treatment is directed at a portion of the intact breast but not the whole breast. The chart may have terms such as MammoSite, interstitial (seed) implant, or (accelerated) partial breast irradiation. Consider the possibility of partial breast irradiation when intensity-modulated radiation therapy (IMRT) is documented in the record.
42	Chest wall	Treatment encompasses the chest wall (following mastectomy).
50	Esophagus	Treatment is directed at all or a portion of the esophagus. Include tumors of the gastro-esophageal junction.

Code	Label	Definition
51	Stomach	Treatment is directed at all or a portion of the stomach.
52	Small bowel	Treatment is directed at all or a portion of the small bowel.
53	Colon	Treatment is directed at all or a portion of the colon.
54	Rectum	Treatment is directed at all or a portion of the rectum.
55	Anus	Treatment is directed at all or a portion of the anus.
56	Liver	Treatment is directed at all or a portion of the liver.
57	Biliary tree or gallbladder	Treatment is directed at all or a portion of the biliary tree or gallbladder.
58	Pancreas or hepatopancreatic ampulla	Treatment is directed at all or a portion of the pancreas or the hepatopancreatic ampulla. Hepatopancreatic ampulla tumors are sometimes referred to as periampullary tumors.
59	Abdomen (NOS)	The treatment volume is directed at a primary tumor of the abdomen, but the primary sub-site is not an abdominal organ defined by codes 50-58 or it is considered to be an unknown primary. For example, this code should be used for sarcomas arising from the abdominal retroperitoneum.
60	Bladder - whole	Treatment is directed at all the bladder.
61	Bladder - partial	Treatment is directed at a portion of the bladder but not the whole bladder.
62	Kidney	Treatment is directed at all or a portion of the kidney.
63	Ureter	Treatment is directed at all or a portion of the ureter.
64	Prostate - whole	Treatment is directed at all the prostate and/or seminal vesicles. Use this code even if seminal vesicles are not explicitly targeted.
65	Prostate - partial	Treatment is directed at a portion of the prostate but not the whole prostate.
66	Urethra	Treatment is directed at all or a portion of the urethra.
67	Penis	Treatment is directed at all or a portion of the penis. Treatments of urethral primaries should be coded as urethra (code 66).
68	Testicle or scrotum	Treatment is directed at all or a portion of the testicle and/or scrotum.
70	Ovaries or fallopian tubes	Treatment is directed at all or a portion of the ovaries or fallopian tubes.
71	Uterus or Cervix	Treatment is directed at all or a portion of the uterus, endometrium, or cervix.
72	Vagina	Treatment is directed at all or a portion of the vagina. Treatments of urethral primaries should be coded as urethra (code 66).
73	Vulva	Treatment is directed at all or a portion of the vulva. Treatments of urethral primaries should be coded as urethra (code 66).
80	Skull	Treatment is directed at all or a portion of the bones of the skull. Any brain irradiation is a secondary consequence.

Code	Label	Definition
81	Spine/vertebral bodies	Treatment is directed at all or a portion of the bones of the spine/vertebral bodies, including the sacrum. Spinal cord malignancies should be coded using spinal cord (code 14).
82	Shoulder	Treatment is directed to all or a portion of the proximal humerus, scapula, clavicle, or other components of the shoulder complex.
83	Ribs	Treatment is directed at all or a portion of one or more ribs.
84	Hip	Treatment is directed at all or a portion of the proximal femur or acetabulum.
85	Pelvic bones	Treatment is directed at all or a portion of the bones of the pelvis other than the hip or sacrum.
86	Pelvis (NOS, non-visceral)	The treatment volume is directed at a primary tumor of the pelvis, but the primary sub-site is not a pelvic organ or is not known or indicated. For example, this code should be used for sarcomas arising from the pelvis.
88	Extremity bone, NOS	Treatment is directed at all or a portion of the bones of the arms or legs. This excludes the proximal femur (hip, code 84). This excludes the proximal humerus (shoulder, code 82).
90	Skin	Treatment is directed at all or a portion of the skin. The primary malignancy originates in the skin and the skin is the primary target. So-called skin metastases are usually subcutaneous and should be coded as a soft tissue site.
91	Soft tissue	This category should be used to code primary or metastatic soft tissue malignancies not fitting other categories.
92	Hemibody	A single treatment volume encompassing either all structures above the diaphragm, or all structures below the diaphragm. This is almost always administered for palliation of widespread bone metastasis in patients with prostate or breast cancer.
93	Whole body	Treatment is directed to the entire body included in a single treatment.
98	Other	Radiation therapy administered; treatment volume other than those previously categorized by codes 01-93.
99	Unknown	This category should be used to code treatments for which there is no information available about the treatment volume, or it is unknown if radiation treatment was administered.

Source: STORE 2021

Table 3. Anatomic sites - examples

Code	Reason
98	A man with a history of prostate cancer and prior radical prostatectomy is treated with SBRT to 3500cGy in five fractions to a recurrent tumor in a remnant right seminal vesicle. Record Phase I Radiation Primary Treatment Volume as code 98 because there is no specific code for seminal vesicles.
93	A woman with advanced multiple myeloma is referred for total body irradiation and is treated twice daily for three consecutive days in a total body stand at extended distance with open rectangular photon fields, 200cGy to mid-body per treatment. Record Phase I Radiation Primary Treatment Volume as code 93 (whole body).

Source: STORE 2021

3.2.1.2 Nodes

Variable name:	p1_node, p2_node, p3_node

Description: Identifies draining lymph nodes, if any, treated during Phase I-II-III of RT
Format: Numeric
Length: 2
Valid values: 00-08, 88

Example: 05

Instruction: When the anatomic target is lymph nodes, draining lymph nodes are not targeted and 88 should be recorded.

The p2_node and p3_node data fields should be left blank for RO beneficiaries receiving one phase of RT. The p3_node data field should be left blank for RO beneficiaries receiving two phases of RT.

Table 4. Draining lymph nodes

Code	Label
00	No radiation treatment to draining lymph nodes
01	Neck lymph node regions
02	Thoracic lymph node regions
03	Neck and thoracic lymph node regions
04	Breast/chest wall lymph node regions
05	Abdominal lymph nodes
06	Pelvic lymph nodes
07	Abdominal and pelvic lymph nodes
08	Lymph node region, NOS
88	Not applicable; Phase I Radiation Primary Treatment Volume is lymph nodes
99	Unknown if any radiation treatment to draining lymph nodes; unknown if radiation treatment administered

Source: STORE 2021

Table 5. Draining lymph nodes - examples

Code	Reason
04	A patient with breast cancer was treated with whole breast RT, 5040 cGy in 28 fractions. Axillary and supraclavicular (SC) nodes treated concurrently with an anterior field covering both regions and a posterior field (PAB) added to the axilla. The medial portion of the anterior field was blocked for the last three treatments to hold the SC region to a maximumof 4500cGy to minimize the risk of brachial plexus injury. Subsequently, the surgical bed received an electron boost of 1000cGy in 5 fractions using fields shaped to surround surgical bed with 1.5 cm margins. Record the Phase I Radiation to Draining Lymph Nodes as 04 (breast/chest wall lymph node regions). See Table 9 for a detailed discussion of this example.
06	Prostate cancer patient declines surgery for management of his prostate cancer and opts for EBRT. The treatment summary states that pelvis/prostate were targeted on Phase I with 180 cGy X 25 fx= 45 Gy. Record Phase I Radiation to Draining Lymph Nodes as 06 because when the pelvis is specifically mentioned in the treatment summary, we can assume that regional lymph nodes were targeted.

Source: STORE 2021

3.2.1.3 Dose per fraction

Variable name: p1_dose, p2_dose, p3_dose

Description: Dose per fraction delivered to the patient, in centrigray (cGy)
Format: Numeric
Length: 5
Valid values: 00001 – 99997, 99998, 99999

Example: 06500

Instructions: Record the actual dose delivered (NOT the initially prescribed dose or the dose planned).

For proton treatment, dosage may occasionally be specified as in CGe units (Cobalt Gray Equivalent) rather than Gy or cGy. 1 CGE = 1 Gy = 100 cGy. For a Phase Total Dose, you would need to multiply dose in CGE by 100 to get dose in cGy.

Dose is still occasionally specified in “rads.” 1 rad = 1cGy.

If dose documented in the medical record includes a fraction of a cGy (e.g. 180.3), round to the nearest cGy. For example, 180.5 cGy should be rounded up to 181 cGy and 180.4 cGy should be rounded down to 180 cGy.

Code 99998 when radioisotopes were administered to the patient.

Code the actual cGy if available when brachytherapy was administered to the patient. If the dose is not available/provided in cGy for a brachytherapy procedure, code 99999.

The p2_dose and p3_dose data fields should be left blank for RO beneficiaries receiving one phase of RT. The p3_dose data field should be left blank for RO beneficiaries receiving two phases of RT.

Table 6. Dosing - examples

Code	Reason
00180	A patient with breast cancer was treated with whole breast RT, 5040 cGy in 28 fractions, but axillary and supraclavicular (SC) nodes were treated concurrently with an anterior field covering both regions and a posterior field (PAB) added to the axilla.The medial portion of the anterior field was blocked for the last three treatments to hold the SC region to a maximum of 4500cGy to minimize the risk of brachial plexus injury. Subsequently, the surgical bed received an electron boost of 1000cGy in 5 fractions using fields shaped to surround surgical bed with 1.5 cm margins. Record Phase I dose per fraction as 00180 (4500/25). See Table 9 for a detailed discussion of this example.
00200	A patient with Stage III prostate carcinoma received pelvic irradiation to 5,000 cGy over 25 fractions followed by a Phase II (boost) prostate irradiation to 7,000 cGy. Record the Phase I dose per fraction as 00200 (5000/25).

Source: STORE 2021

3.2.1.4 Fractions

Variable name: p1_frac, p2_frac, p3_frac

Description: Number of fractions delivered to the patient in the phase
Format: Numeric
Length: 3
Valid values: 001-998, 999

Example: 025

Instructions: Record the actual number of fractions (NOT initially prescribed), when the two numbers differ.

Although a fraction or treatment session may include several treatment beam positions delivered within a relatively confined period of time—usually a few minutes to a few hours—it is still considered one fraction. However, multiple fractions may be delivered in a single day. This may be documented as BID treatment or twice daily treatment. Usually multiple fractions in a single day are separated by at least 4 hours.

Count each separate administration of brachytherapy or implant as a single fraction or treatment.

Code 999 if Phase I RT was administered, but the number of fractions is unknown.

The p2_frac and p3_frac data fields should be left blank for RO beneficiaries receiving one phase of RT. The p3_frac data field should be left blank for RO beneficiaries receiving two phases of RT.

Table 7. Fractions - examples

Code	Reason
025	A patient with breast carcinoma had treatment sessions in which treatment was delivered to the chest wall and encompassing the ipsilateral supraclavicular region fora total of three fraction portals. Twenty-five treatment sessions were given. Record 25 fractions as 025.
001	Prostate cancer patient treated with a single administration of seeds. Record 1 fraction as 001.

Source: STORE 2021

3.2.1.5 Total dose per phase

Variable name: p1_tot_dose, p2_tot_dose, p3_tot_dose

Description: Total radiation dose delivered to the patient in the phase, in centrigray (cGy)
Format: Numeric
Length: 6
Valid values: 000001 – 999997, 999998

Example: 006500

Instructions: Record the actual total dose delivered (NOT initially prescribed or planned).

Code 999998 if radioisotopes are administered to the patient.

For proton treatment, dosage may occasionally be specified as in CGE units (Cobalt Gray Equivalent) rather than Gy or cGy. 1 CGE = 1 Gy = 100 cGy. For a Phase Total Dose, you would need to multiply dose in CGE by 100 to get dose in cGy.

Dose is still occasionally specified in “rads”. 1 rad = 1 cGy.

If dose documented in the medical record includes a fraction of a cGy (e.g., 180.3), round to the nearest cGy. For example, 180.5 cGy should be rounded up to 181 cGy and 180.4 cGy should be rounded down to 180cGy.

Code the actual cGy if available when brachytherapy was administered to the patient. If only one fraction of brachytherapy was delivered, then the Phase I Dose per Fraction and the Phase I Total Dose will be the same.

The p2_tot_dose and p3_tot_dose data fields should be left blank for RO beneficiaries receiving one phase of RT. The p3_tot_dose data field should be left blank for RO beneficiaries receiving two phases of RT.

Table 8. Total dose for phase - examples

Code	Reason
004500	A patient with breast cancer was treated with whole breast RT, 5040 cGy in 28 fractions, but axillary and supraclavicular (SC) nodes treated concurrently with an anterior field covering both regions and a posterior field (PAB) added to the axilla. The medial portion of the anterior field was blocked for the last three treatments to hold the SC region to a maximum of 4500 cGy to minimize the risk of brachial plexus injury. Subsequently, the surgical bed received an electron boost of 1000 cGy in 5 fractions using fields shaped to surround surgical bed with 1.5 cm margins. Record the Phase I Total Dose of 4500 cGy as 004500. See Table 9 for a detailed discussion of this example.
005000	A patient with Stage III prostate carcinoma received pelvic irradiation of 5,000 cGy in 25 fractions during Phase I Radiation Treatment. Record the Phase I Total Dose of 5,000 cGy as 005000.

Source: STORE 2021

Why collect such detailed dosage and fraction data? *When several sites are treated during the same episode, the total dose and number of fractions per site will be used to understand practice patterns, facilitate monitoring, and possibly inform development of quality measures related to dose, including hypofractionation.*

Clinical Scenario - Putting it all Together

In this section, we explain how anatomic target, node, fraction, and dose variables are documented for two clinical scenarios.

Table 9. Clinical scenario 1

Clinical					
• A 46 year-old female with T2N1M0 breast cancer s/p lumpectomy of 5 nodes positive. ER 100%, PR 10%, HER-2 negative. ER = estrogen receptor PR = progesterone receptor HER-2 = human epidermal growth factor receptor 2					
Treatment					
• Whole breast RT, 5040 cGy in 28 fractions given between 8/13/2018 and 9/19/2018 using 6Mv photons, conformal fields. • Axillary and supraclavicular (SC) nodes treated concurrently with 6Mv photons using an anterior field covering both regions to deliver a daily dose of 180 cGy to a depth of 3 cm. Because the radiation intensity diminishes with depth, a posterior axillary field (PAB) was added delivering 30 cGy per day to the midplane of the axilla so this region also received the prescribed daily dose of 180 cGy. • The medial portion of the anterior field was blocked for the last three treatments to hold the SC region to a maximum of 4500 cGy to minimize the risk of brachial plexus injury. • Between 9/20 and 9/26 the surgical bed received an electron boost of 1000 cGy in 5 fractions using fields shaped to surround surgical bed with 1.5 cm margins.					
Phase I		Phase II		Phase III	
Anatomic site 40 Breast - whole		*Anatomic site:* 40 Breast - whole		*Anatomic site* 41 Breast – partial[c]	
Draining nodes 04 Breast/chest wall lymph node region[a]		*Draining nodes* 04 Breast/chest wall lymph node region[b]		*Draining nodes* 00 No RT to nodes	
Fractions	025	*Fractions*	003	*Fractions*	005
Dose per fraction	00180 cGy	*Dose per fraction*	00180 cGy	*Dose per fraction*	00200 cGy
Total dose	004500 cGy	*Total dose*	000540 cGy	*Total dose*	001000 cGy
Explanation		Explanation		Explanation	
[a] In this phase the code 04 for draining nodes represents both axillary and SC regions as a single target.		[b] In this phase, the code 04 for draining nodes represents just the axilla, as it receives three additional treatments. Note that the PAB is simply regarded as part of the axillary plan and not coded as a phase.		[c] This is what is commonly called the “boost” or “cone down” to deliver additional radiation to the region at greatest risk for recurrence, the surgical bed.	

Source: CTR Guide to Coding Radiation Therapy Treatment in the STORE (V3.0).

NOTE: In this example, although the whole breast received 28 fractions with a dose of 180 cGY per fraction, it is split into two phases. Phase I includes the 25 fractions where the radiation was delivered to the whole breast and to the SC and axillary nodes. Phase II includes the 3 fractions where radiation was delivered to the whole breast and axillary nodes only. The SC nodes were blocked when the 3 additional fractions were delivered. STORE does not provide enough granularity to distinguish between the possible combinations of targets in this region, so the 04 Breast/chest wall LN region code is used for both Phase I and Phase II.

Table 10. Clinical scenario 2

Clinical

- A 74-year-old woman underwent lumpectomy followed by breast irradiation for a pT2 (2.3cm) pN1a cM0, ER 100%, PR 90%, HER-2 negative, left breast cancer.

ER = estrogen receptor PR = progesterone receptor HER-2 = human epidermal growth factor receptor 2

Treatment

Two prescriptions:

- Regional (breast plus axillary lymph nodes) treatment to a prescribed dose of 4005 cGy (267 cGy per day) in 15 fractions.
- Simultaneous treatment of lumpectomy bed with margins to a prescribed dose of 320 cGy per day for a total of 4800 cGy.

Phase I		Phase II		Phase III
Anatomic site 41 Breast - partial		*Anatomic site:* 40 Breast - whole		
Draining nodes 00 No RT to nodes		*Draining nodes* 04 Breast/chest wall lymph node regions[a]		
Fractions	015	*Fractions*	015	
Dose per fraction	00320 cGy	*Dose per fraction*	00267 cGy	
Total dose	004800 cGy	*Total dose*	004005 cGy	

NOTES

While treatment to both prescription areas occurred simultaneously, there were two prescriptions and therefore two phases. The only question is which treatment should be considered Phase I, the prescription with the larger volume or the prescription with the higher total dose. The standard is to assign Phase I to the target volume receiving the highest dose.

[a] Axillary treatment is a physical extension of breast treatment and therefore assigned to Phase II.

Source: CTR Guide to Coding Radiation Therapy Treatment in the STORE (V3.0).

3.3 Breast Cancer Clinical Data Elements

3.3.1 Cancer stage

Variable names: ajcc_t ajcc_n ajcc_m

Description: Extent and spread of tumor
Format: Alphanumeric
Length: Varies (see the following tables containing valid values)
Example: ajcc_t = T2; ajcc_n = N1; ajcc_m = M0

Instructions: Record the AJCC T, N, and M values that are documented closest to the start of the 90-day episode, which could be before the start of the episode.

T refers to the size and extent of the main tumor.

N refers to the number of nearby lymph nodes that have cancer.

M refers to whether the cancer has metastasized.

Breast Cancer—AJCC TNM (8th Edition)					
ajcc_t		**ajcc_n**			**ajcc_m[a]**
TX	T2	NX	N1a	N3a	M0
T0	T3	N0	N1b	N3b	M0(i+)
Tis(DCIS)	T4	N0(i+)	N1c	N3c	M1
Tis(Paget)	T4a	N0(mol+)	N2		
T1	T4b	N1	N2a		
T1mi	T4c	N1mi	N2b		
T1a	T4d		N3		
T1b					
T1c					

[a] There is no MX. Unless there is clinical or pathological evidence of distant metastases, the patient is classified as clinical M0.

3.3.2 Intent of treatment

Variable name: intent

Description: Intent of treatment
Format: Integer
Length: 1

Valid values: 1 = Palliative
2 = Curative

Instructions: Record the RO beneficiary's intent of treatment for the RO episode. If the intent of treatment is documented more than once and the intent differs, record the intent that is documented closest to the start of the RO episode, which could be before the start of the episode.

3.3.3 Histology

Variable name:	histo

Description: Tumor histology
Format: Integer
Length: 1

Valid values:
1 = Ductal carcinoma in situ
2 = Infiltrating ductular carcinoma
3 = Lobular carcinoma
4 = Invasive carcinoma with ductal and lobular features (mixed-type carcinoma)
7 = Other
9 = Not available

Instructions: Record the histology of the RO beneficiary's breast cancer treated during the RO episode. If histology is reported multiple times, report the histological information documented closest to the start of the RO episode, which could be before the start of the episode.

"9 = Not available" should only be used if histology is unknown and the intent of the RO beneficiary's treatment is palliative.

3.3.4 Laterality

Variable name:	laterality

Description: Side of treatment
Format: Integer
Length: 1

Valid values:
1 = Right
2 = Right and left
3 = Left

Instructions: Record the laterality of the RO beneficiary's breast cancer treated during the RO episode. If laterality is documented at multiple points in time, report the laterality that is documented closest to the start of the RO episode, which could be before the start of the episode.

3.4 Prostate Cancer Clinical Data Elements

3.4.1 Cancer stage

Variable names: ajcc_t ajcc_n ajcc_m

Description: Extent and spread of tumor
Format: Alphanumeric
Length: Varies (see tables below containing valid values)
Example: ajcc_t = T2; ajcc_n = N1; ajcc_m = M0

Instructions: Record the AJCC T, N, and M values that are documented closest to the start of the RO episode, which could be before the start of the episode.

T refers to the size and extent of the main tumor.

N refers to the number of nearby lymph nodes that have cancer.

M refers to whether the cancer has metastasized.

Prostate Cancer—AJCC TNM (8th Edition)				
ajcc_t		**ajcc_n**	**ajcc_m[a]**	
TX	T2a	NX	M0	M1b
T0	T2b	N0	M1	M1c
T1	T2c	N1	M1a	
T1a	T3			
T1b	T3a			
T1c	T3b			
T2	T4			

[a] There is no MX. Unless there is clinical or pathological evidence of distant metastases, the patient is classified as clinical M0.

3.4.2 Intent of treatment

Variable name: intent

Description: Intent of treatment
Format: Integer
Length: 1

Valid values: 1 = Palliative
2 = Curative

Instructions: Record the RO beneficiary's intent of treatment for the RO episode. If the intent of treatment is documented more than once and the intent differs, record the intent that is documented closest to the start of the RO episode, which could be before the start of the episode.

3.4.3 ISUP Grade Group or Gleason score

- Report the RO beneficiary's International Society of Urological Pathology (ISUP) Grade Group or Gleason score.[9]
- If the ISUP Grade Group or Gleason score is documented more than once in the RO beneficiary's medical record, report the ISUP Grade Group or Gleason score that is documented closest to the start of the RO episode.
- If the ISUP Grade Group and Gleason score are documented on the same date closest to the start of the RO episode, report the ISUP Grade Group, which could be before the start of the episode.

3.4.3.1 ISUP Grade Group

Variable name: isup

Description: ISUP Grade Group
Format: Integer
Length: 1

Valid values: 1 = ISUP Grade Group 1
2 = ISUP Grade Group 2
3 = ISUP Grade Group 3
4 = ISUP Grade Group 4
5 = ISUP Grade Group 5

3.4.3.2 Gleason score

Variable name: gleason

Description: Gleason score
Format: Integer
Length: 1

Valid values: 1 = Gleason score <=6
2 = Gleason score 7 (3+4)
3 = Gleason score 7 (4+3)
4 = Gleason score 8
5 = Gleason score 9 or 10

[9] Descriptions corresponding to the ISUP Grade Groups and equivalent Gleason scores can be found in Patel, K.M., and V.J. Gnanapragasam. "Novel Concepts for Risk Stratification in Prostate Cancer." *Journal of Clinical Urology*, vol. 9, 2016, pp. 18–23.

3.5 Lung Cancer Clinical Data Elements

3.5.1 Cancer stage

Variable names: ajcc_t ajcc_n ajcc_m

Description: Extent and spread of tumor
Format: Alphanumeric
Length: Varies (see the following table containing valid values)
Example: ajcc_t = T2; ajcc_n = N1; ajcc_m = M0

Instructions: Record the AJCC T, N, and M values that are documented closest to the start of the RO episode, which could be before the start of the episode.

T refers to the size and extent of the main tumor.

N refers to the number of nearby lymph nodes that have cancer.

M refers to whether the cancer has metastasized.

Lung Cancer—AJCC TNM (8th Edition)				
ajcc_t			ajcc_n	ajcc_m[a]
TX	T1b	T3	NX	M0
T0	T1c	T4	N0	M1
Tis	T2		N1	M1a
T1	T2a		N2	M1b
T1mi	T2b		N3	M1c
T1a				

[a] There is no MX. Unless there is clinical or pathological evidence of distant metastases, the patient is classified as clinical M0.

3.5.2 Intent of treatment

Variable name: intent

Description: Intent of treatment
Format: Integer
Length: 1

Valid values: 1 = Palliative
2 = Curative

Instructions: Record the RO beneficiary's intent of treatment for the RO episode. If the intent of treatment is documented more than once and the intent differs, record the intent that is documented closest to the start of the RO episode, which could be before the start of the episode.

3.5.3 Histology

Variable name: histo

Description: Tumor histology
Format: Integer
Length: 1

Valid values: 1 = Non-small-cell lung cancer
2 = Small-cell lung cancer
3 = Pleural neoplasm
7 = Other
9 = Not available

Instructions: Record the histology of the RO beneficiary's lung cancer treated during the RO episode. If histology is reported multiple times, report the histological information documented closest to the start of the RO episode, which could be before the start of the episode.

"9 = Not available" should only be used if histology is unknown and the intent of the RO beneficiary's treatment is palliative.

3.6 Bone Metastases

3.6.1 Prior RT to an overlapping area

Variable name: overlap

Description: RT to an overlapping area
Format: Integer
Length: 1

Valid values: 0 = No 1 = Yes

Instructions: Indicate if the RO beneficiary ever received RT services, before the start of the RO episode, to the area(s) irradiated during the RO episode. The previous RT services can partially or fully overlap the area irradiated during the RO episode.

3.7 Brain Metastases

3.7.1 Prior RT to brain

Variable name: prev_brain_tx

Description: Prior RT to the brain
Format: Integer
Length: 1

Valid values: 0 = No 1 = Yes

Instructions: Indicate if the RO beneficiary ever received RT to the brain before the start of the RO episode.

3.8 Timelines for Reporting Clinical Data Elements

All Professional participants and Dual participants must submit CDEs biannually for RO beneficiaries who were treated for applicable cancer types and completed their RO episode in the preceding six months. CDEs are reported within the month of July for episodes completed between January 1 and June 30 and within the month of January for episodes completed between July 1 and December 31.

3.9 Successful Reporting of Clinical Data Elements

The Innovation Center will consider Professional participants and Dual participants to have successfully submitted their clinical data elements if they submit CDEs (1) by the deadline specified and (2) for at least 95 percent of RO beneficiary episodes who completed during the performance year.

Data completeness example: An RO participant has 48 RO beneficiaries who completed their RO episode for the treatment of prostate cancer between January 1 and June 30. RO participants will upload CDEs to the RO Secure Data Portal in July of the performance year. To receive pay-for-reporting credit, all data fields must be populated for at least 95 percent of the RO beneficiaries; the RO participant must submit complete data for 46 of its 48 RO beneficiaries (that is, 48 * 95 percent = 45.6, rounded to the nearest whole number).

Multiple episode example: An RO beneficiary with bone metastases has an RO episode that begins in early May and is completed in early July. The same RO beneficiary has a second RO episode, for bone metastases, that starts in early September and is completed in late October. In this case, the RO beneficiary would be reported two times on the bone metastases CDE template submitted in January; one row would represent the episode ending in early July and the second row would represent the episode ending in late October.

3.10 Clinical Data Element Reporting Templates

RO participants can access the CDE templates for prostate, breast, and lung cancer and bone and brain metastases through the RO Secure Data Portal. CDE templates are in Microsoft® Excel format.

3.11 Clinical Data Element Submission Procedure

RO participants will submit CDE data files via the RO Secure Data Portal. More information about data submission, including the process for uploading files, submission deadlines, and data validation, can be found in the RO Model Secure Data Portal User Manual at https://innovation.cms.gov/media/document/ro-portal-usermanual.

4. Quality Measures

4.1 Overview

The RO Model is designed to preserve or enhance quality of care. Professional participants and Dual participants are therefore required to report aggregate data on four quality measures each year.

In addition to the four quality measures, RO beneficiaries will be invited to participate in the CAHPS® Cancer Care Survey for Radiation Therapy[10] with the Shared Decision Making module,[11] funded by the Innovation Center and administered by the RO Implementation and Monitoring Contractor. Quality measure scores and CAHPS® survey results will be incorporated into RO participants' AQS (see Section 5).

Quality measures will be reported at the TIN-NPI level and will include all patients receiving RT services from those included on the individual practitioner list certified in the RO Administrative Portal (ROAP).

These data will enable the Innovation Center to measure the impact of the RO Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. RO participants will have an opportunity to earn back a portion of the quality and patient experience withholds based on CDE reporting, applicable quality measure reporting and performance, and the beneficiary-reported CAHPS® Cancer Care Radiation Therapy Survey (see Section 5 for additional details). Table 11 lists the quality measures included in the RO Model.

Table 11. Quality measures

Full measure title	Shortened name (if applicable)	NQF ID CMS ID (if applicable)	Measure steward
Oncology: Medical and Radiation—Plan of Care for Pain	N/A	NQF #0383 CMS #144	American Society of Clinical Oncology
Preventive Care and Screening: Screening for Depression and Follow-Up Plan	N/A	NQF #0418 CMS #134	CMS
Advance Care Plan	N/A	NQF #0326 CMS #047	National Committee for Quality Assurance
Treatment Summary Communication—Radiation Oncology	N/A	n.a.	American Society for Radiation Oncology
CAHPS® Cancer Care Survey for Radiation Therapy with Shared Decision Making module	N/A	n.a.	Agency for Healthcare Research and Quality

[10] https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cancer/rad-eng-cancer-551a.pdf
[11] https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cancer/suppl-items-cancer-english-557a.pdf

4.2 Quality Measure Terminology

Professional participants and Dual participants will report, at the TIN-NPI level, the total number of patients that satisfy each component of the measure—that is, the denominator and numerator. RO participants will also report the total number of patients meeting denominator and numerator exclusion and exception criteria, if applicable.

Table 12 contains definitions of relevant quality measure components for PY1. Professional participants and Dual participants should carefully review all quality measure specifications, accessible via the links provided in Table 11, to prepare systems at the start of PY1 to capture the data needed for complete and timely reporting. As a reminder, RO participants are not responsible for administering the CAHPS® Cancer Care Survey for Radiation Therapy.

Table 12. Components of quality measures

Measure component	Description	Examples
Denominator	All events (such as patients or visits) to be evaluated by a performance measure that share certain common characteristics within a specific measurement set to which the performance measure belongs	• All patients ages 65 and older with an eligible encounter during the measurement period • All visits for patients, regardless of age, with a diagnosis of cancer who are currently receiving RT and who report pain
Denominator exclusion	Events (such as patients or visits) that should be removed from the measures before determining whether the numerator criteria are met	• Patients who received hospice services at any time during the measurement period
Numerator	Processes or outcomes expected for each patient, procedure, or other unit of measurement defined in the denominator	• Visits that included a documented plan of care to address pain

Note: Additional measure components include denominator exceptions, numerator exclusions, and numerator exceptions. The quality measures for PY1 do not contain these elements, and thus they do not appear in Table 12.

4.3 RO Model Quality Measures

This section briefly describes each quality measure and the CAHPS® Cancer Care Survey for Radiation Therapy. In addition, using the Plan of Care for Pain measure (CMS #144), we provide an example of how an RO participant would determine their aggregate counts.

Detailed quality measure specifications can be found via the links in Table 11.

The quality measure specifications for the 2022 Merit-Based Incentive Payment System (MIPS) reporting period can be found via the links contained in Table 11.

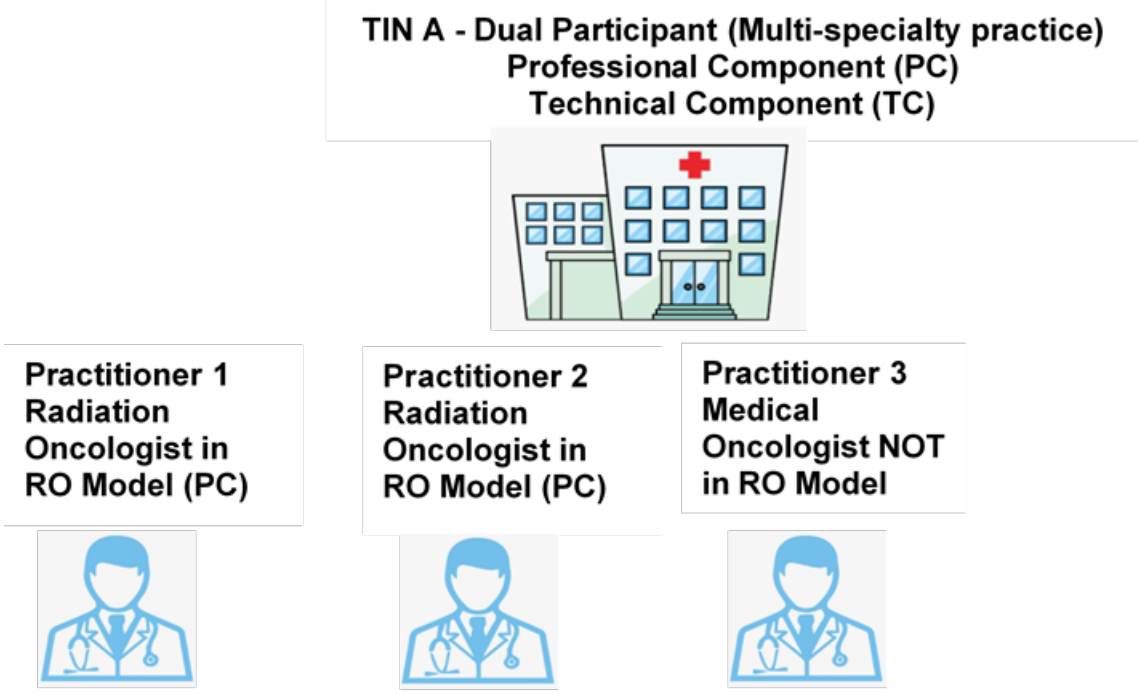
4.3.1 Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS #144)

The Oncology: Medical and Radiation—Plan of Care for Pain measure, stewarded by the American Society of Clinical Oncology (ASCO), is a process measure that assesses whether patients with cancer who report having pain have a documented plan of care for pain. Specifically, the measure reflects the percentage of visits for patients, regardless of age, who have a diagnosis of cancer, are currently receiving chemotherapy or RT, and have moderate or severe pain for which there is a documented plan to address pain in the first two visits. This measure is designed to improve attention to pain management and requires plans of care to enable individualized treatment.

The measure numerator includes patient visits that involved a documented plan of care to address pain. The measure denominator includes all visits for patients, regardless of age, who have a diagnosis of cancer, are currently receiving chemotherapy or RT, and report moderate or severe pain.

Oncology: Medical and Radiation – Pain Intensity Quantified (NQF #0384; CMS #143) is often reported in parallel with the Plan of Care for Pain measure (CMS #144). To reduce burden, Professional participants and Dual participants are NOT required to report CMS #143. Although reporting is not required, patients' pain will need to be quantified, in accordance with CMS #143 measure specification, to determine if denominator criteria for CMS #144 are met.

4.3.1.1 Sample Measure Calculation for Plan of Care for Pain Quality Measure



Patient	Visits with Mod to Severe Pain	Plan for Pain
A	5	3
B	6	4
C	12	6
D	5	0
E	8	2
F	7	3
TOTAL	**43**	**18**

Patient	Visits with Mod to Severe Pain	Plan for Pain
A	1	0
B	2	1
C	1	0
G	8	2
H	6	1
I	15	5
TOTAL	**33**	**9**

Patient	Visits with Mod to Severe Pain	Plan for Pain
A	3	0
J	12	2
K	8	6
L	4	0
TOTAL	**27**	**8**

Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS #144)

The measure denominator includes all visits for patients with an attributed Professional Component practitioner, regardless of age, who have a diagnosis of cancer, are currently receiving chemotherapy or RT, and report moderate or severe pain.

Denominator = 43 (Practitioner 1) + 33 (Practitioner 2) = 76
Numerator = 18 (Practitioner 1) + 9 (Practitioner 2) = 27

In the HDR, the RO participant enters 76 in the denominator field and 27 in the numerator field.

NOTE: Practitioner 3 is not a radiation oncologist. As a result, they will not be on the individual practitioner list certified in the RO Administrative Portal (ROAP). Therefore, all visits to Practitioner 3, RO beneficiary or otherwise, are excluded from the reporting of the Oncology: Medical and Radiation—Plan of Care for Pain quality measure.

4.3.2 Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS #134)

The Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure, stewarded by CMS, is a process measure that assesses the percentage of patients who are screened for clinical depression with an age-appropriate, standardized tool and who have had a follow-up care plan documented in their medical record. Screening and treating the potential mental health effects of RT is important because depression is often a comorbidity to cancer care and some of the side effects of RT have been found to lower a patient's quality of life and could extend beyond physical discomfort.

The measure numerator includes patients screened for depression on the date of the encounter using an age-appropriate standardized tool and, if the screening is positive, a follow-up plan is documented on the date of the positive screen. The measure denominator includes all patients ages 12 and older before the start of the measurement period who have at least one eligible encounter during the measurement period.

4.3.3 Advance Care Plan (NQF #0326; CMS #047)

The Advance Care Plan measure, stewarded by the National Committee for Quality Assurance (NCQA), is a process measure that describes the percentage of patients ages 65 and older who have (1) an advance care plan or surrogate decision maker documented in the medical record, or (2) documentation in the medical record that an advance care plan was discussed, but the patient did not wish to or could not provide such a plan or name a surrogate decision maker. This measure focuses on personalized care and alignment of care with patient goals.

The measure numerator includes patients who have (1) an advance care plan or surrogate decision maker documented in the medical record, or (2) documentation in the medical record that an advance care plan was discussed, but the patient did not wish to or could not provide such a plan or name a surrogate decision maker. The measure denominator includes all patients ages 65 and older, but it excludes patients receiving hospice services.

4.3.4 Treatment Summary Communication—Radiation Oncology

The Treatment Summary Communication measure, stewarded by the American Society for Radiation Oncology (ASTRO), is a process measure that assesses the percentage of patients, regardless of age, who have a diagnosis of cancer, have undergone brachytherapy or external beam RT, and have a treatment summary report in their chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment. Specifically, this measure assesses care coordination and communication between providers during transitions of cancer care treatment and recovery.

The measure numerator includes patients who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment. The measure denominator includes all patients, regardless of age, who have a diagnosis of cancer and have undergone brachytherapy or external beam RT.

The Treatment Summary Communication measure will be included in the RO Model as a pay-for-reporting measure during PY1 and PY2, until a benchmark is established that will enable performance on this measure to be included in the AQS beginning in PY3.

4.3.5 CAHPS® Cancer Care Survey for Radiation Therapy

The Innovation Center will assess patient experience using the CAHPS® Cancer Care Survey for Radiation Therapy with the inclusion of the supplemental shared decision-making items.[12] The CAHPS® survey is funded by the Innovation Center and administered by the RO Implementation and Monitoring Contractor to all RO beneficiaries.

RO participants are <u>not</u> responsible for the administration of or payment for the CAHPS® Cancer Care Survey.

Administration of the CAHPS® Cancer Care Survey will begin in the fourth month of the model performance period for patients completing their RO episode during the first three months of the RO Model. Patients completing their RO episode will be added to the survey sample quarterly. CAHPS® results will be included in the AQS beginning in PY3.

4.4 Quality Measure Reporting Timeline

RO participants will submit annual, aggregate quality measure data by March 31 for the preceding calendar year (CY). For example, RO participants must submit their aggregate quality measure data for episodes completed in PY1 no later than March 31 of the following CY. The measure specifications should be used to identify denominator-eligible patients who should be included in aggregate quality measure data reporting.

4.5 Quality Measure Reporting Mechanism

Professional participants and Dual participants will submit quality measure data via the RO Secure Data Portal.

Instructions for uploading quality measure data can be found in the RO Model Secure Data Portal User Manual at https://innovation.cms.gov/media/document/ro-portal-usermanual. The RO Secure Data Portal can be found at https://portal.cms.gov.

[12] Agency for Healthcare Research and Quality. "CAHPS® Cancer Care Survey: Radiation Therapy." 2016. Available at https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cancer/rad-eng-cancer-551a.pdf. Shared Decision Making module available at: https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cancer/suppl-items-cancer-english-557a.pdf. Accessed April 5, 2022.

4.6 RO Participants Already Reporting Quality Measures

RO participants might already be reporting one or more of the quality measures to satisfy reporting requirements for other programs, such as MIPS. If so, RO participants should continue to submit the measure data to that program's reporting mechanism, based on that program's requirements.

Professional participants and Dual participants will also submit quality data required by the RO Model separately via the RO Secure Data Portal.

4.7 Eligible Population for Quality Measures

Reporting of aggregate quality measure data is not limited to Medicare or Medicare-eligible patients. All patients seen by radiation oncologists included on the individual practitioner list certified in ROAP are included in quality measure reporting, as appropriate, based on the measure specifications.

Quality measures are reported for all patients seen by radiation oncologists who are participating in the RO Model.

4.8 Minimum Case Threshold

The RO Model will not score measures for Professional participants or Dual participants that do not have at least 20 eligible cases, according to the specifications for each measure. An RO participant with fewer than 20 applicable cases will enter ''n.a./insufficient cases'' in the reporting template for the measure, whether it is pay-for-reporting or pay-for-performance. See section 5.2.3. Low-volume allowance.

5. Aggregate Quality Score

5.1 AQS Background

The AQS is a numeric score calculated for each RO participant. It is based on each Professional participant's or Dual participant's (1) performance on the selected RO Model quality measures; (2) reporting of data for any measures designated as pay-for-reporting (those without established performance benchmarks); and (3) reporting of CDEs on applicable RO beneficiaries.

Failure to report timely and complete CDEs will lower the RO participant's AQS.

5.2 AQS Methodology

The RO Model quality measures will be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exist. Table 13 shows the designations for each measure in the RO Model and the corresponding program year for which the assigned designation applies.

Table 13. Measures and contribution to the AQS

	Level of reporting	Contribution to AQS calculation	
		Pay-for-reporting	Pay-for-performance
Oncology: Medical and Radiation—Plan of Care for Pain NQF #0383 / CMS #144	Aggregate	n.a.	PYs 1–5
Preventive Care and Screening: Screening for Depression and Follow-Up Plan NQF #0418 / CMS #134	Aggregate	n.a.	PYs 1–5
Advance Care Plan NQF #0326 / CMS #047	Aggregate	n.a.	PYs 1–5
Treatment Summary Communication—Radiation Oncology	Aggregate	PYs 1–2	PYs 3–5
CAHPS® Cancer Care Survey	Patient-reported	n.a.	PYs 3–5
Clinical data elements	RO beneficiary	PYs 1-5	n.a.

5.2.1 Pay-for-performance

Each Professional participant's and Dual participant's performance rates on each pay-for-performance measure will be compared against applicable MIPS program benchmarks.[13] In PY1 and PY2, three quality measures will be pay-for-performance: Advance Care Plan, Plan of Care for Pain, and Screening and Follow-Up for Depression. For each measure, the RO participant can earn up to 10 points or 30 points for all three measures. As discussed in Section 5.2.3 and 5.2.5 below, measures will take on additional weight in PY1 and PY2 or in the event of a low volume-allowance.

[13] For example, 2021 quality benchmarks can be found at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.

5.2.2 Pay-for-reporting

Quality measures can also be scored as pay-for-reporting. In PY1 and PY2, the Treatment Summary Communication measure will be pay-for-reporting, with RO participants receiving 10 points for successfully submitting aggregate quality measure data. As discussed in Section 5.2.3 and 5.2.5 below, measures will take on additional weight in PY1 and PY2 or in the event of a low volume-allowance.

CDEs are scored as pay-for-reporting in each performance year. RO participants submitting complete and timely CDE data will receive 50 points.

5.2.3 Low-volume allowance

Professional participants and Dual participants might not have enough eligible cases (fewer than 20) to report a given measure. When this occurs, the measure will be excluded from the RO participant's AQS denominator calculation and the remaining measures will be adjusted to reach a denominator of 50 points. This recalibration is intended to make certain that participants do not receive any benefit or penalty for having insufficient cases for a measure.

5.2.4 Penalty for nonreporting

If a Professional participant or Dual participant fails to report complete and timely CDE data, it will receive 0 of 50 points for CDE reporting. Partial points will not be awarded if CDE data are submitted in a timely fashion for fewer than 95 percent of RO beneficiaries.

If a Professional or Dual participant fails to report aggregate data on a required quality measure, it will receive 0 of 10 points for the non-reported quality measure(s).

5.2.5 AQS Calculation

Fifty percent of the RO participants' AQS is based on the successful reporting of required CDEs. The other 50 percent is based on quality measure reporting and, where applicable, performance on those measures. Mathematically, AQS scoring is expressed as follows:

> **AQS = quality measures** (0 to 50 points based on weighted measure scores and reporting) **+ CDEs** (50 points when data are submitted for ≥95 percent of applicable RO beneficiaries)

In PY1 and PY2, four quality measures contribute to the AQS. As a result, the points earned for quality measures will be recalibrated to a denominator of 50 points. The Innovation Center will process AQS calculations as early as August of the following PY, concurrent with the reconciliation process (e.g., PY1 AQS calculations will be done in August of PY2).

5.2.6 AQS Sample Calculation

PY1 Scenario:	**AQS Calculation**:
RO participant has 100 RO beneficiaries with an applicable cancer type[14] who complete their RT episode in the PY	
Complete CDE reporting by RO participant for 98 of 100 RO beneficiaries completing RO episodes in the PY	**50 points** for CDE reporting
RO participant meets the reporting threshold for three of the four quality measures: Advance Care Plan, Plan of Care for Pain, and Treatment Summary Communication	Eligible for 30 points
RO participant submits aggregate quality measure data for the treatment plan summary measure (pay-for-reporting)	**10 points** for pay-for-reporting quality measure (Treatment Summary Communication)
Practitioner submits aggregate data for Advance Care Plan and Plan of Care for Pain quality measures (pay-for-performance)	**6 points** for the Advance Care Plan quality measure score based on comparison with MIPS program benchmark **4 points** for the Plan of Care for Pain quality measure based on comparison with MIPS program benchmark
	20 quality measure points earned out of 30 **Adjust to a 50-point scale: (20 * 50 / 30) = 33.3** **33.3 quality measure points + 50 CDE points = 83.3 points** **RO participant earns back 1.67 percent of the 2.0 percent quality withhold [2.0 percent * (83.3/100)]**

[14] Breast, prostate, and lung cancer and bone and brain metastases.