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

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Change Log

Date	Version	Description of change
11/01/2021	2	Modified language to indicate that reporting of clinical data elements and quality measure reporting is optional in Performance Year 1 (PY1).
11/01/2021	2	Simplified reporting of primary anatomic target, fractions, dose, total dose, nodes, and boost for breast, prostate, and lung cancer.
11/01/2021	2	Modified language to indicate that CDEs will be reported within cancer-specific tabs within a single Microsoft® Excel workbook.
11/01/2021	2	Included content indicating that Professional participants and Dual participants will be provided a Microsoft® Excel workbook populated, by cancer type, with their RO Model ID, RO beneficiary Medicare Beneficiary Identifiers (MBIs) for whom they are to report clinical data elements, and start of episode date for each RO beneficiary.
11/01/2021	2	Modified language to indicate that the 2-percent quality withhold will not be applied to RO Model Payments in PY1 (2022).
12/08/2021	3	Updated the description of the Oncology: Medical and Radiation—Plan of Care for Pain measure (NQF #0383; CMS #144) to be consistent with the 2021 MIPS CQM measure specification.
12/08/2021	3	Added language about the Advance Care Plan (NQF #0326; CMS #047) and licensing agreement requirements.

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, beginning January 1, 2022. 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. The Microsoft® Excel CDE workbook 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 may optionally report in Performance Year 1 (PY1).
- **Section 4** discusses the quality measures (QMs) that RO participants may optionally report in Performance Year 1 (PY1).
- **Section 5** discusses the Aggregate Quality Score (AQS) methodology.

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.[1]

- 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 start of episode (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).

[1] 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.
- **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.[2]
- **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 will be implemented in PY1 and 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. Reporting of CDEs is optional in PY1; reporting will be required starting in PY2.
  - **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. Reporting of quality measures is optional in PY1; reporting will be required starting in PY2.

Professional participants and Dual participants can optionally report CDEs and quality measures in PY1. Reporting will be required starting in PY2.

[2] 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 Professional participants and Dual participants to download their Microsoft® Excel CDE workbook, upload their workbook populated with CDEs, and input aggregate quality measure data directly.

3. Clinical Data Elements

Professional participants and Dual participants, in PY1, may optionally report CDEs for RO beneficiaries treated with an included RT service for one or more of the five included cancer types: (1) prostate, (2) breast, (3) lung, (4) bone metastases, and (5) brain metastases. Table 1 shows the data elements available for reporting.

Starting in PY2 (2023), reporting of CDEs will be required for Professional participants and Dual participants for all 5 cancer types.

This section describes the CDEs that Professional participants and Dual participants may optionally report in PY1 and will be required to report starting in PY2 for RO beneficiaries who completed their RO episode during the reporting period.[3] 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.

Table 1. Clinical data elements

	Breast	Prostate	Lung	Bone metastases	Brain metastases
ECOG or KPS score	✓	✓	✓	✓	✓
AJCC TNM staging	✓	✓	✓		
Intent of treatment	✓	✓	✓		
Primary anatomic target	✓	✓	✓		
Fractions	✓	✓	✓		
Dose per fraction	✓	✓	✓		
Total dose	✓	✓	✓		
Regional nodes	✓	✓			
Boost	✓				
Histology	✓		✓		
Laterality	✓				
ISUP Grade Group or Gleason score		✓			
Prior RT to an overlapping area				✓	
Prior RT to brain					✓

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.

Professional and Dual participants will be provided with a Microsoft® Excel CDE workbook populated with RO Model ID, RO beneficiary MBIs that should be included in CDE reporting for the 6-month reporting period, and start of episode date for each RO beneficiary. The Microsoft® Excel CDE workbook will be available for download, via the Secure Data Portal, approximately three months prior to the July 31st and January 31st reporting deadlines.

NOTE: CMMI seeks to minimize the burden associated with CDE reporting. CMMI is currently engaging with electronic health record (EHR) and RO information system vendors to develop electronic extracts that can be submitted in lieu of the Microsoft® Excel CDE workbook.

[3] Although unlikely, the Innovation Center may make adjustments to CDEs, if necessary, prior to the start of PY2.

3.1. Clinical Data Elements Common Across Included Cancer Types

One CDE is common across the five included cancer types (prostate, breast, and lung cancers, and bone and brain metastases) —performance status.

3.1.1. Performance status

- Report either the Eastern Cooperative Oncology Group (ECOG) performance status score[4] or the Karnofsky Performance Score (KPS) score[5] for each RO beneficiary.
- The intent is to record the ECOG or KPS score upon which decisions about the RT treatment plan are based. 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.

3.1.1.1. 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

[4] ECOG-ACRIN Cancer Research Group. "ECOG Performance Status." n.d. Available at https://ecog-acrin.org/resources/ecog-performance-status. Accessed March 22, 2021
[5] 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.

3.1.1.2. 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. Clinical Data Elements Common Across Breast, Prostate, and Lung Cancers

Reporting cancer stage (TNM), intent of treatment, primary anatomic target, dose, fraction, total dose, regional nodes, and boost for all RO beneficiaries treated for breast cancer, prostate cancer, and lung cancer **is optional in PY1. Reporting of these data will be required in subsequent PYs**.

3.2.1. 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 90-day episode, which could be before the start of the episode. Ideally, this will be the TNM stage on which decisions about RT were based.

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

N refers to whether nearby lymph nodes have cancer.

M refers to whether the cancer has metastasized.

When available, pathologic stage should be reported. Otherwise report clinical stage.

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.

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.

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.

3.2.2. 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.

If the intent of treatment is documented as "non-curative," record "palliative."

3.2.3. Primary anatomic target

Variable name:	prim_anat

Description: Identifies the primary treatment volume or primary anatomic target treated.
Format: Numeric
Length: 2
Valid values: 40-42, 98 (breast); 64-65, 98 (prostate); 30-31, 39, 98 (lung)

Instruction: Indicate the primary anatomic target, which is typically the primary tumor or tumor bed.

Valid values:

Breast cancer

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).
98	Other	Radiation therapy administered; treatment volume other than those previously categorized by codes 40-42.

Definitions from the Standard for Oncology Registry Entry manual (STORE) 2021.

Prostate cancer

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	Prostate bed (post-operative)	Treatment is directed at the prostate bed, post-operatively.
98	Other	Radiation therapy administered; treatment volume other than those previously categorized by codes 64-66.

Definitions are from the Standard for Oncology Registry Entry manual (STORE) 2021 except for '66', which was defined by the RO Model team.

Lung cancer

30	Lung or bronchus	Treatment is directed at all or a portion of the lung or bronchus, and may also include regional lymph nodes.
31	Mesothelium	Treatment is directed to all or a portion of the mesothelium, and may also include regional lymph nodes. This code should be used for mesothelioma primaries, even if a portion of the lung is included in the radiation field.
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.
98	Other	Radiation therapy administered; treatment volume other than those previously categorized by codes 30-31, 39.

Definitions from the Standard for Oncology Registry Entry manual (STORE) 2021.

3.2.4. Dose per fraction to primary anatomic target

Variable name: dose

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

Example: 06500

Instructions: Record the actual dose per fraction delivered to the primary anatomic target (NOT the initially prescribed dose or the dose planned). There are instances where dose per fraction may vary across the course of treatment. In these cases, report the dose per fraction that was most frequently delivered. See Table 2, Scenario #3 for an example.

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

Dose per fraction is still occasionally specified in "rads." 1 rad = 1cGy.

If the dose per fraction 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.

3.2.5. Fractions to primary anatomic target

Variable name:	frac

Description: Number of fractions delivered to the primary anatomic target
Format: Numeric
Length: 3
Valid values: 001-998, 999

Example: 025

Instructions: Record the actual number of fractions delivered to the primary anatomic target (NOT initially prescribed), when the two numbers differ.

Code 1 when radioisotopes were administered to the patient.

3.2.6. Total dose to primary anatomic volume

Variable name:	tot_dose

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

Example: 006500

Instructions: Record the **actual total dose delivered** to the primary anatomic target (NOT the initially prescribed dose or the dose planned).

For proton treatment, dose may occasionally be specified as in CGE units (Cobalt Gray Equivalent) rather than Gy or cGy. 1 CGE = 1 Gy = 100 cGy. For 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.

Some radiation plans may include multiple target volumes receiving different doses. Please report the dose for the primary anatomic target (see 3.2.1). Boost dose and dose to regional nodes are NOT included in the total dose calculation.

Code 99998 when radioisotopes were administered to the patient.

3.2.7. Regional nodes

Variable name:	nodes

Description: Indicates if radiation was delivered to the regional nodes for RO beneficiaries with breast or prostate cancer.
Format: Numeric
Length: 1

Valid values: 0 = No
1 = Yes

Instructions: Regional node data are reported for **breast and prostate cancer only**.

3.2.8. Boost

Variable name:	boost

Description: Indicates if a boost was administered in the treatment of breast cancer.
Format: Numeric
Length: 1

Valid values: 0 = No
1 = Yes
Instructions: Boost data are reported for **breast cancer only**.

Clinical Scenario - Putting it all Together

In this section, we explain how primary anatomic target, fractions, dose per fraction, total dose, regional nodes, and boost are documented for three clinical scenarios.

Table 2. Clinical scenarios

Scenario #1
A patient with Stage II prostate carcinoma received whole prostate irradiation of 7,400 cGy in 37 fractions. Pelvic lymph nodes were not treated.
Primary anatomic target 64 Prostate - whole
Fractions 037
Dose per fraction 00200 cGy
Total dose 007400 cGy
Regional nodes 0

Scenario #2

A patient with breast cancer was treated with whole breast RT, 5040 cGy in 28 fractions, with 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.

Primary anatomic target	40 Breast - whole
Fractions	028
Dose per fraction	00180 cGy
Total dose	005040 cGy
Regional nodes	1
Boost	1

Explanation: Total dose, dose per fraction, and number of fractions are reported only for the primary anatomic target. Therefore, in this scenario only the total dose, dose per fraction, and number of fractions to the whole breast are reported: 5040 cGy in 28 fractions, with a dose per fraction of 180 cGy.

Because regional nodes were also treated, regional nodes are coded as YES. However, total dose, dose per fraction, and number of fractions to the supraclavicular field are not reported.

Similarly, boost will be coded as YES. However, the boost total dose, dose per fraction, and number of fractions, which is given to a smaller volume than the whole breast, is not recorded.

Scenario #3

A patient with metastatic lung cancer is receiving palliative RT to the lung. The radiation oncologist planned for the patient to receive 3000 cGy in 10 fractions, with 300 cGy per fraction. However, after receiving 6 out of 10 fractions, the patient indicates that he would prefer to spend more time with family and less time receiving treatment. As a result, the plan is revised so that the final 4 fractions are condensed into 2 fractions of 400 cGy per fraction.

Primary anatomic target	30 Lung or bronchus
Fractions	08
Dose per fraction	00300 cGy
Total dose	002600 cGy

Explanation: The total dose delivered to this patient was 300 cGy x 6 fractions + 400 cGy x 2 fractions = 2600 cGy. A total of 8 fractions were delivered. The dose per fraction that was most frequently delivered was 300 cGy.

3.3. Breast Cancer Clinical Data Elements

3.3.1. 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, biopsy not done

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, biopsy not done" should only be used in cases where a biopsy was NOT performed.

3.3.2. 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. ISUP Grade Group or Gleason score

- Report the RO beneficiary's International Society of Urological Pathology (ISUP) Grade Group or Gleason score.[6]
- 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.

3.4.1.1. 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

3.4.1.2. 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

[6] 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. 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, biopsy not done

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, biopsy not done" should only be used in cases where a biopsy was NOT performed.

3.6. Bone Metastases

3.6.1. Prior RT to an overlapping area

Variable name:	overlap

Description: RT to an overlapping area
Format: Numeric
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: Numeric
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

In PY1, Professional participants and Dual participants may optionally report CDEs biannually for RO beneficiaries who 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

Beginning in PY2, the Innovation Center will consider Professional participants and Dual participants to have successfully submitted their clinical data elements if they submit complete CDEs (1) by the deadline specified and (2) for at least 95 percent of RO beneficiary episodes 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).

Beginning in PY2, to receive pay-for-reporting credit, all CDEs must be reported for at least 95 percent of RO beneficiaries completing their 90-day episode in the preceding six months.

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 Workbook

RO participants can access their Microsoft® Excel CDE workbook with tabs for prostate, breast, and lung cancer and bone and brain metastases through the RO Secure Data Portal.

3.11. Clinical Data Element Submission Procedure

RO participants will submit their Microsoft® Excel CDE workbook via the RO Secure Data Portal. More information about data submission, including the upload process, 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 will therefore be required to report aggregate data on four quality measures beginning in PY2. **Reporting of quality measure data in PY1 is optional.**

Beginning in PY1, RO beneficiaries will be invited to participate in the CAHPS® Cancer Care Survey for Radiation Therapy[7] with the Shared Decision Making module,[8] 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 beginning in PY2 and PY3 respectively (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 3 lists the quality measures included in the RO Model.

Table 3. 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[a]	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

[a] A hyperlink to the Advance Care Plan measure specification will be added once it becomes available on the National Committee for Quality Assurance (NCQA) website.

[7] https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cancer/rad-eng-cancer-551a.pdf.
[8] 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 4 contains definitions of relevant quality measure components for the quality measures described in Table 3. Professional participants and Dual participants should carefully review all quality measure specifications, accessible via the links provided in Table 3, to prepare systems 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.

Some quality measures include data from each patient visit while others include data reflecting a quality action that occurs across all visits occurring during the measurement period. RO participants should carefully review the quality measure specifications to understand reporting requirements.

Table 4. 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 4.

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 3.

The quality measure specifications for the 2022 Merit-Based Incentive Payment System (MIPS) reporting period can be found via the links contained in Table 3.

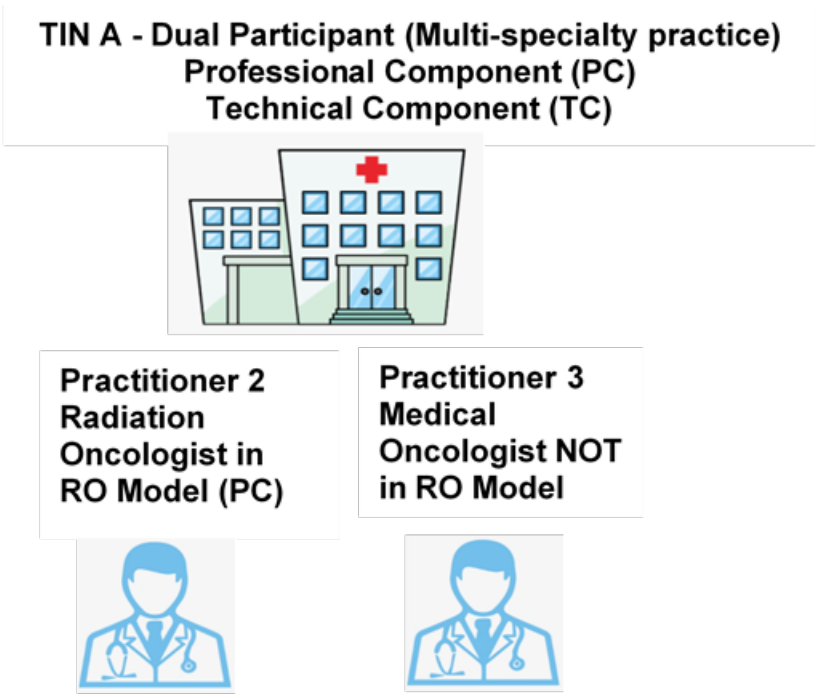
4.3.1. Oncology: Medical and Radiation—Plan of Care for Pain (NQF #0383; CMS #144)

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, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain. 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 with a diagnosis of cancer who are currently receiving chemotherapy or RT and report pain being present.

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 Pain Reported	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 Pain Reported	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 Pain Reported	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 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 aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. A standardized tool is defined as a normalized and validated depression screening tool developed for the patient population in which it is being utilized. Although examples of depression screening tools are listed within the measure specification, RO participants are not limited to these as long as a normalized and validated depression screening tool is used. 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.

4.3.3.1. Advance Care Plan Measure and Licensing Agreement

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) has been in discussions with the National Committee for Quality Assurance (NCQA) to ensure that CMS may continue to access, collect, utilize, and report quality measure data from NCQA measures for purposes of the RO Model. CMS has entered into a short-term license agreement with NCQA ("License Agreement") to allow CMS, its direct contractors, and Model Participants to collect and report the following NCQA measure[s]: Advance Care Plan.

The License Agreement is now in effect and allows CMS, its direct contractors, and Model Participants to use and reference the Licensed Measure Specifications for the above measure[s] for the term of the License Agreement, subject to the conditions described in the License Agreement. In addition, under the terms of the License Agreement, NCQA has agreed to display the full Licensed Measure Specifications and associated value sets on NCQA's website, free of charge, for access by Model Participants for use in the Model only. However, the License Agreement does not extend to third parties who contract with, or otherwise assist, Model Participants in performing services related to the Model as it pertains to the above measure[s]. Such third party entities may include, but are not limited to, vendors (e.g., EHR/EMR vendors), data collection or reporting organizations, and other similar entities under contract with, or otherwise assist, Model participants with performing services related to the Model. Third parties who contract with, or otherwise assist, Model Participants to perform services related to the Model will require a separate license agreement with NCQA to access and use the Licensed Measure Specifications. Such a license is at the discretion of NCQA.

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 cancer diagnosis 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 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.[9] 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.

[9] 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.

Administration of the CAHPS® Cancer Care Survey will begin in July of PY1 and include all RO beneficiaries completing their RO episode during the first six months of the RO Model. Thereafter, RO beneficiaries 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

Professional participants and Dual participants will submit annual, aggregate quality measure data by March 31 for the preceding calendar year (CY). For example, RO participants opting to report quality measure data for episodes completed in PY1 will submit aggregate data no later than March 31, 2023. The measure specifications should be used to identify denominator-eligible patients who should be included in aggregate quality measure data reporting.

Reporting of quality measures in PY1 is optional and will occur no later than March 31, 2023. Required reporting will begin in PY2, with the first submission no later than March 31, 2024.

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.

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

Reporting of CDEs and quality measures is optional in PY1**. The CAHPS® Cancer Care Survey will be administered starting in PY1. However, it will not contribute to the AQS until PY3 (see Table 5). As a result, **the 2-percent quality withhold will not be applied to RO Model Payments in PY1 (2022).

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.

Beginning in PY2, 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 5 shows the designations for each measure in the RO Model and the corresponding program year for which the assigned designation applies.

Table 5. 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 2–5
Preventive Care and Screening: Screening for Depression and Follow-Up Plan NQF #0418 / CMS #134	Aggregate	N/A	PYs 2–5
Advance Care Plan NQF #0326 / CMS #047	Aggregate	N/A	PYs 2–5
Treatment Summary Communication—Radiation Oncology	Aggregate	PYs 2	PYs 3–5
CAHPS® Cancer Care Survey	Patient-reported	N/A	PYs 3–5
Clinical data elements	RO beneficiary	PYs 2-5	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.[10] In 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 PY2 or in the event of a low volume-allowance.

5.2.2. Pay-for-reporting

Quality measures can also be scored as pay-for-reporting. In 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 the event of a low volume-allowance.

CDEs are scored as pay-for-reporting in each performance year, beginning in PY2. 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 quality 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

Beginning in PY2, 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).

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

5.2.5. 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 complete data are submitted for ≥95 percent of applicable RO beneficiaries)

Starting in PY2, four quality measures will 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., PY2 AQS calculations will be done in August of PY3).

5.2.6. AQS Sample Calculation

PY2 Scenario:	**AQS Calculation**:
RO participant has 100 RO beneficiaries with an applicable cancer type[11] 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)]**

REMINDER: Reporting of CDEs and quality measures is optional in PY1*. The CAHPS® Cancer Care Survey will be administered starting in PY1. However, it will not contribute to the AQS until PY3 (see Table 5). As a result, in PY1,* ***the 2-percent quality withhold will not be applied to RO Model Payments in PY1 (2022).***

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