

United States Department of Health  
and Human Services

REPORT TO CONGRESS:

Episodic Alternative Payment Model for  
Radiation Therapy Services

November 2017

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## **Commonly Used Terms and Abbreviations in Radiation Therapy**

<b>3DCRT</b>	3-dimensional Conformal Radiation Therapy
<b>AAPM</b>	Advanced Alternative Payment Model
<b>ACO</b>	Accountable Care Organization
<b>ACS</b>	American Cancer Society
<b>ACR</b>	American College of Radiology
<b>APC</b>	Ambulatory Payment Classification
<b>APM</b>	Alternative Payment Model
<b>ADCC</b>	Alliance of Dedicated Cancer Centers
<b>AFROC</b>	Association of Freestanding Radiation Oncology Centers
<b>ASCO</b>	American Society of Clinical Oncologists
<b>ASTRO</b>	American Society for Radiation Oncology
<b>BCPI</b>	Bundled Care Payments for Improvement
<b>CAH</b>	Critical Access Hospital
<b>CAHPS</b>	Consumer Assessment of Healthcare Providers and Systems
<b>CAN</b>	Cancer Action Network
<b>CEHRT</b>	Certified Electronic Health Record Technology
<b>CFR</b>	Code of Federal Regulations
<b>CHIP</b>	Children’s Health Insurance Program
<b>CMCH</b>	Community Mental Health Center
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>COA</b>	Community Oncology Alliance
<b>CTCAE</b>	Common Terminology Criteria for Adverse Events
<b>CY</b>	Calendar Year
<b>E&amp;M</b>	Evaluation and Management
<b>EPM</b>	Episode Payment Model
<b>FFS</b>	Fee for Service
<b>GCPI</b>	Geographic Practice Cost Index
<b>HCPCS</b>	Healthcare Common Procedure Coding System
<b>HDR</b>	High Dose Rate
<b>HHS</b>	Department of Health and Human Services
<b>HWI</b>	Hospital Wage Index
<b>ICD-9</b>	International Classification of Diseases, Ninth Revision
<b>ICD-10</b>	International Classification of Diseases, Tenth Revision
<b>ICU</b>	Intensive Care Unit

<b>IGRT</b>	Image-guided Radiation Therapy
<b>IMRT</b>	Intensity-modulated Radiation Therapy
<b>IPPS</b>	Inpatient Prospective Payment System
<b>LCD</b>	Local Coverage Determination
<b>LDR</b>	Low Dose Rate
<b>LINAC</b>	Linear Accelerator
<b>LOI</b>	Letter of Intent
<b>MAC</b>	Medicare Administrative Contractor
<b>MACRA</b>	Medicare Access and CHIP Reauthorization Act of 2015
<b>MEOS</b>	Monthly Enhanced Oncology Services
<b>MIPS</b>	Merit-based Incentive Payment System
<b>NCCN</b>	National Comprehensive Cancer Network
<b>NCD</b>	National Coverage Determination
<b>NCI</b>	National Cancer Institute
<b>OCM</b>	Oncology Care Model
<b>OPD</b>	Outpatient Departments
<b>OPPS</b>	Outpatient Prospective Payment System
<b>PAMPA</b>	Patient Access and Medicare Protection Act
<b>PBPM</b>	Per-Beneficiary-Per-Month
<b>PE</b>	Practice Expense
<b>PFPM</b>	Physician-focused Payment Model
<b>PFS</b>	Physician Fee Schedule
<b>PPECH</b>	Prospective Payment-Exempt Clinical Hospital
<b>PTAC</b>	Physician-focused Payment Model Technical Advisory Committee
<b>QCDR</b>	Qualified Clinical Data Registry
<b>RTA</b>	Radiation Therapy Alliance
<b>RVU</b>	Relative Value Unit
<b>SBRT</b>	Stereotactic Body Radiation Therapy
<b>SEER</b>	Survey of Epidemiology and End Results
<b>SRS</b>	Stereotactic Radiosurgery
<b>US</b>	United States

## **1. Executive Summary**

Section 3(b) of the Patient Access and Medicare Protection Act (PAMPA) (P.L. 114-115) directs the Secretary of Health and Human Services to submit a report to Congress on the development of an episodic alternative payment model (APM) for Medicare payment under title XVIII of the Social Security Act (the Act) for radiation therapy services furnished in non-facility settings.<sup>1</sup> The Centers for Medicare & Medicaid Services (CMS) has prepared this report to respond to this requirement.

The Center for Medicare and Medicaid Innovation (CMS Innovation Center), a component within CMS, supports the development and testing of innovative health care payment and service delivery models. The CMS Innovation Center has been studying the cost, utilization, and quality of cancer treatment with radiation therapy; consulting with radiation therapy stakeholders; and considering design elements to develop this Report to Congress on an episodic APM for radiation therapy. This Report to Congress addresses each of these topics while exploring key design elements for a radiation therapy services episodic APM.

## **2. Legislation**

PAMPA was enacted on December 28, 2015. Section 3(a) of the PAMPA revised the Medicare Physician Fee Schedule (PFS) payment for radiation treatment and related imaging services by mandating that CMS apply the same code definitions, work relative value units (RVUs) and “direct inputs” for the practice expense RVUs in 2017 and 2018 that applied in 2016. Section 3(a) of the PAMPA also exempted certain radiation therapy and related imaging services from being considered as potentially misvalued services under CMS’ misvalued codes initiative for 2017 and 2018. Finally, section 3(b) of the PAMPA directed the Secretary of Health and Human Services to submit to Congress a report on the development of an episodic alternative payment model for payment under the Medicare program under title XVIII of the Social Security Act (the Act) for radiation therapy services furnished in non-facility settings. The full text of Section 3 of PAMPA is available in Appendix A.

## **3. Incidence of Cancer**

In 2017, the National Cancer Institute and the American Cancer Society (ACS) estimate there will be 1,688,780 new cancer cases and 600,920 cancer deaths.<sup>2</sup> The ACS also reported that the lifetime probability for developing cancer from 2010 to 2012 was 42.1% for males and 37.6% for females while the probability of cancer death for this period was 22.6% for males and 19.1% for females.<sup>3</sup> These statistics underscore the burden of cancer on the American public. Table 1 summarizes the ACS projections of new cancer cases and deaths in 2017.

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<sup>1</sup> Patient Access and Medicare Protection Act Pub. L. No. 114-115, 129 Stat 3131 (2015).

<sup>2</sup> NCI: <https://seer.cancer.gov/statfacts/html/all.html> and American Cancer Society. (n.d.) Cancer Statistics Center. <https://cancerstatisticscenter.cancer.org/#/>.

<sup>3</sup> American Cancer Society Surveillance Research. (2016). Lifetime Probability of Developing and Dying from Cancer for 23 Sites, 2010-2012. Retrieved from <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2016/lifelong-probability-of-developing-and-dying-from-cancer-for-23-sites-2010-2012.pdf>.

**Table 1: Estimated New Cancer Cases and Deaths, Both Sexes 2017**

Cancer Type	New Cancer Cases	Deaths
Breast	255,180	41,070
Lung/bronchus	222,500	155,870
Prostate	161,360	26,730
Colorectal	135,430	50,260
Pancreatic	53,670	43,090
Oral cavity and pharynx	49,670	9,700
Brain/other nervous system	23,800	16,700
Esophagus	16,940	15,690
Larynx	13,360	3,660
Cervix	12,820	4,210
Soft issue (including heart)	12,390	4,990
Gallbladder and other biliary	11,740	3,830
Hodgkin’s lymphoma	8,260	1,070
Anus/Anal canal/Anorectal	8,200	1,100
Vulva	6,020	1,150
Vagina/other female genital	4,810	1,240
Bones and joints	3,260	1,550
Eye and orbit	3,130	330
Penis and other male genital	2,120	360

The National Cancer Institute also estimates that the costs for cancer therapy in 2010 in the United States reached more than \$124 billion, representing 5% of total health care spending; the figure is projected to reach \$157 billion by 2020.<sup>4</sup> In 2010, the most expensive cancers to treat were breast (\$16.5 billion), colorectal (\$14.1 billion), lymphoma (\$12.1 billion), lung (\$12.1 billion), and prostate (\$11.9 billion).<sup>5</sup>

## 4. Radiation Therapy Services

Radiation therapy is a common treatment for nearly two thirds of all patients undergoing cancer treatment<sup>6 7</sup> and is typically furnished by a radiation oncologist. In the United States, patients made an estimated 20.94 million radiation treatment visits to 2,340 sites in 2012.<sup>8</sup> Of these visits, 43% were non-

<sup>4</sup> Sullivan, R., Peppercorn, J., Sikora, K., Zalberg, J., Meropol, N. J., Amir, E., & Fojo, T. (2011). Delivering affordable cancer care in high-income countries. *The lancet oncology*, 12(10), 933-980.

<sup>5</sup> Ibid.

<sup>6</sup> Physician Characteristics and Distribution in the U.S., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

<sup>7</sup> This 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division.

<sup>8</sup> IMV Medical Information Division. (2013). Benchmark Report Radiation Therapy 2012-2013.



hospital visits, 11% were visits to hospitals with less than 200 beds, 23% were to hospitals with 200–399 beds, and 23% to hospitals with 400-plus beds.<sup>9</sup>

Radiation therapy is used in four primary circumstances: to reduce the size of a tumor prior to surgery (neoadjuvant therapy), as primary therapy (definitive therapy), post-operatively (adjuvant therapy), and for palliative treatment. It is often a primary therapy for prostate, lung, breast, brain and brain metastases, head and neck, gynecological, skin, and other types of cancer as well as non-malignant conditions. Radiation therapy can be used as standalone treatment or as part of a treatment regimen that includes chemotherapy and/or surgery. For example, depending on the extent of disease, a patient’s individual characteristics, and scientific data supporting clinical decision-making, the treatment for head and neck cancer can be radiation therapy only, concurrent chemotherapy and radiation therapy, or alternating radiation therapy and chemotherapy.<sup>10</sup>

From 2000 to 2010, the volume of physician billing for radiation treatment increased 8.2%, while Medicare Part B payments for radiation treatment increased 216%.<sup>11</sup> Researchers indicate this increase in payments for radiation during this period was primarily due to significant uptake in a certain type of radiation therapy (Intensity-Modulated Radiation Therapy, or “IMRT”).<sup>12</sup> In another study, researchers predicted that, “from 2010 to 2020, the demand for radiation therapy during the initial treatment course is expected to increase by 22% (from 470,000 patients receiving radiation therapy in 2010 to 575,000 patients receiving radiation therapy in 2020) as a result of the aging and diversification of the US population.”<sup>13</sup>

For the same period (2010–2020), the number of adults age 65 and older requiring radiation therapy during the initial treatment course is projected to increase 38% (from 282,000 to 388,000) compared with a 1.7% increase (from 188,000 to 191,000) for individuals younger than age 65 treated with radiation therapy.<sup>14</sup>

## **4.1 Settings of Care Where Radiation Therapy is Furnished**

Section 3(b) of PAMPA directed the Secretary to “submit to Congress a report on the development of an episodic alternative payment model...for radiation therapy services furnished in nonfacility settings.” The term “non-facility settings” refers to freestanding radiation therapy centers, which are treated like physicians’ offices for Medicare payment and billing purposes, and are paid under the Medicare Physician Fee Schedule. In contrast, the term “facility settings” refers to hospitals, which provide radiation therapy in their hospital outpatient departments.<sup>15</sup> The terms “freestanding radiation therapy center” and “hospital outpatient department” are used throughout this report in place of the terms “non-facility” and “facility”,

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<sup>9</sup> Ibid.

<sup>10</sup> Peterman, A., Cella, D., Glandon, G., Dobrez, D., & Yount, S. (2001). Mucositis in head and neck cancer: economic and quality-of-life outcomes. *J Natl Cancer Inst Monogr*, 29, 45-51.

<sup>11</sup> Shen, X., Showalter, T. N., Mishra, M. V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. *Journal of Oncology Practice*, 10(4), e201-e207.

<sup>12</sup> Ibid.

<sup>13</sup> Smith, B. D., Haffty, B. G., Wilson, L. D., Smith, G. L., Patel, A. N., & Buchholz, T. A. (2010). The Future of Radiation Oncology in the United States from 2010 to 2020: Will Supply Keep Pace with Demand? *Journal of Clinical Oncology*, 28(35), 5160-5165.

<sup>14</sup> Ibid.

<sup>15</sup> A small amount of radiation therapy is also furnished in the hospital inpatient setting.

respectively, as these terms are more commonly used in this context. Further information about the different settings of care where radiation is furnished and how radiation services are paid is discussed in section 4.5 of this report.

Although section 3(b) of the PAMPA directs the Secretary to submit a report on the development of an episodic alternative payment model for radiation therapy services in non-facility settings, this report addresses not only radiation therapy furnished in freestanding radiation therapy centers but also radiation therapy furnished in hospital outpatient departments (which is where a majority of radiation therapy is furnished). Based on CMS's analysis of Medicare claims, in roughly 62 percent of radiation therapy episodes (defined in section 4.2 of this report) between January 1, 2013 and December 31, 2015, a hospital outpatient department furnished the majority of the radiation treatment delivery services.<sup>16</sup> In 38 percent of the episodes, a freestanding radiation therapy center furnished the majority of the radiation treatment delivery services. Where possible, CMS has separated data analyses presented in this report based on the setting of care. In considering an episodic alternative payment model for radiation therapy, we believe it is important to look at how those services are furnished, billed, and paid in both settings. Unless specifically stated, the considerations that this report discusses for an episodic payment model for radiation therapy services do not differ between the settings.

## **4.2 Types of Cancer Treated with Radiation Therapy**

CMS analyzed Medicare fee-for-service (FFS) claims between January 1, 2013 and December 31, 2015 to understand several aspects of radiation services furnished to the Medicare population during that period. CMS used hospital outpatient and physician fee schedule claims, accessed through CMS's Chronic Conditions Data Warehouse (CCW),<sup>17</sup> to identify all beneficiaries who received any radiation treatment delivery services within the 3-year period. These radiation treatment delivery services included various types of external beam radiation therapy (such as 3-dimensional conformal radiation therapy (3DCRT), intensity-modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiation therapy (SBRT) and proton beam therapy) and brachytherapy.<sup>18</sup> Using that group of beneficiaries and their associated Medicare Part A, Medicare Part B, and Medicare Part D claims, CMS conducted several analyses to answer key questions regarding radiation treatment patterns.

CMS isolated courses of radiation to treat cancer, otherwise known as "episodes," during the 3-year period. For purposes of the analysis, an episode was generally defined to include a treatment planning service (which typically started the episode) and one or more treatment delivery services (which must have occurred on a date between three days prior and up to or 28 days after the treatment planning service).<sup>19</sup> Based on additional analyses<sup>20</sup> that indicated the vast majority of radiation courses of treatment were completed within 90 days, the episodes also included services from the day the episode began (usually the day the treatment planning service was furnished) and the subsequent 89 days.

Based on the analysis of Medicare claims, there were about 640,000 episodes of radiation therapy between January 1, 2013 and December 31, 2015, or approximately 210,000 episodes per year.

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<sup>16</sup> Additional information regarding the services that constitute "radiation treatment delivery services" can be found in section 4.4 of this report.

<sup>17</sup> <https://www.ccwdata.org/web/guest/home>.

<sup>18</sup> Radiation treatment delivery services are described further in section 4.3, but generally include those services where radiation is delivered to the patient. It includes HCPCS codes such as G6015 and G6016, which are used to bill for Intensity Modulated Radiation Treatment (IMRT) in freestanding radiation therapy centers.

<sup>19</sup> Additional information regarding treatment planning and delivery services is available in section 4.3.

<sup>20</sup> Described further in section 7.2.3.

As described in section 4.1 of this report, in roughly 62 percent of radiation therapy episodes between January 1, 2013 and December 31, 2015, a hospital outpatient department furnished the majority of the radiation treatment delivery services. In 38 percent of the episodes, a freestanding radiation therapy center furnished the majority of the radiation treatment delivery services. As shown in Table 2, roughly 590,000 unique Medicare beneficiaries had an episode of radiation therapy during that period.

**Table 2: Number of Unique Medicare Beneficiaries and Corresponding Radiation Oncology Episodes, January 1, 2013 – December 31, 2015**

	2013	2014	2015	Total*
<i>Number of Unique Beneficiaries</i>	208,655	208,241	203,810	591,298
<i>Number of Episodes</i>	213,673	213,455	208,912	636,040

*\*Note: The total number of unique Medicare beneficiaries is lower than the total number of episodes because some beneficiaries experienced more than one episode during the 3-year period. In addition, the counts of unique beneficiaries in each year are specific to that year; therefore, a single beneficiary could be counted in 2013, 2014 and/or 2015, but only once in the "Total" column. Said differently, the number of unique beneficiaries for all years ("Total") shows the number of unique beneficiaries across all three years.*

CMS also assigned each episode a “cancer type.” These cancer types were defined by specific ICD-9 and ICD-10 diagnoses codes that we grouped together to represent a “type” of cancer. For this analysis, for example, CMS grouped together ICD-9 codes 174.XX, 175.XX, and 233.0X and ICD-10 codes C50.XX and D05.XX to define “breast cancer” and any beneficiary with an ICD-9 or ICD-10 code in that range would be assigned “breast cancer.” To identify the correct ICD-9 or ICD-10 diagnosis for each episode, CMS identified those diagnoses associated with the beneficiary’s evaluation and management (E&M) services that occurred 60 days prior to the start of the episode and 60 days after the start of the episode. CMS then assigned the most common cancer diagnosis associated with those E&M services to the episode.

Based on the analysis of Medicare claims, roughly 55% of radiation therapy episodes between January 1, 2013 and December 31, 2015 were to treat breast cancer (20.4%), lung cancer (20.0%), or prostate cancer (15.0%). Non-melanoma skin cancer (6.3%), head and neck cancer (5.5%), and lower gastrointestinal (GI) cancer (4.3%) were also commonly treated with radiation. Table 3 and Figure 1 provide additional information about the other cancer types that were treated with radiation.

**Table 3: Medicare Fee-For-Service Episodes of Radiation between January 1, 2013 and December 31, 2015, by Cancer Type**

Cancer Type	Number of Episodes	Percent of Episodes
All Episodes	636,040	100%
Breast Cancer	129,744	20.40%
Lung Cancer	127,066	20.00%
Prostate Cancer	95,654	15.00%
Non-Melanoma Skin Cancer	40,092	6.30%
Head and Neck Cancer	34,882	5.50%
Lower Gastrointestinal	27,333	4.30%
Other Cancers	23,869	3.80%
Secondary Neoplasms	22,030	3.50%
Non-Ovarian Female GU	21,763	3.40%

Cancer Type	Number of Episodes	Percent of Episodes
No Cancer Diagnosis on Claim	19,487	3.10%
Lymphoma	19,881	3.10%
Upper Gastrointestinal	16,822	2.60%
Bladder Cancer	11,631	1.80%
CNS	9,816	1.50%
Malignant Melanoma	8,106	1.30%
Multiple Myeloma	8,487	1.30%
Pancreatic Cancer	8,272	1.30%
Kidney Cancer	6,003	0.90%
Liver Cancer	5,102	0.80%

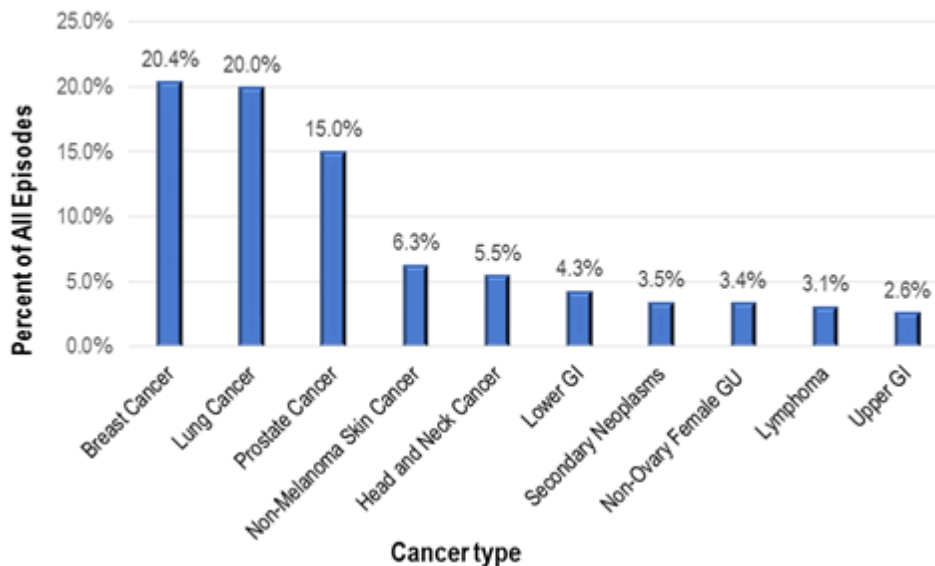


Figure 1: Medicare Fee-For-Service Episodes of Radiation between January 1, 2013 and December 31, 2015, by Cancer Types (top 10)

### 4.3 Types of Radiation Therapy

There are three primary types of radiation therapy: external beam radiation therapy (EBRT), internal radiation therapy (brachytherapy), and infused radiopharmaceuticals.<sup>21</sup>

External-beam radiation therapy is commonly furnished by a linear accelerator (LINAC) machine from outside the body in the form of photon beams (either x-rays or gamma rays). Proton therapy is a type of EBRT that uses protons generated by a cyclotron or synchrotron. Patients usually receive EBRT in daily treatment sessions, Monday to Friday, over the course of several weeks. The number of treatment sessions and total radiation dose depend on many factors, including the specific cancer treated, individual patient characteristics, and available clinical evidence. The techniques for furnishing EBRT include 2DCRT,

<sup>21</sup> National Cancer Institute Radiation (2013) Therapy for Cancer. Available at: <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet#q8>.

3DCRT, IMRT, IGRT, tomotherapy, SRS, SBRT, proton beam therapy, and electron beam therapy.

Another type of radiation therapy treatment is internal radiation therapy or brachytherapy, which entails placing a radioactive isotope sealed inside a tiny seed (pellet) in the patient’s body next to the cancer cells. These isotopes naturally decay and emit radiation that damages nearby cancer cells. Interstitial brachytherapy uses a radiation source placed within tumor tissue such as within a prostate tumor. Intracavity brachytherapy uses a radiation source placed within a surgical cavity or body cavity near the tumor such as a chest cavity. Episcleral brachytherapy is used to treat melanoma inside the eye using a radiation source attached to the eye. Brachytherapy techniques include high dose rate brachytherapy (HDR) and low dose rate (LDR) brachytherapy.

A third major type of radiation therapy treatment is radiopharmaceutical therapy, which uses a radioactive substance given by mouth or into a vein, which can target cancer throughout the body. For example, radioactive iodine is often used to treat certain types of thyroid cancer because thyroid cells naturally take up iodine.

#### 4.4 Services Included in an Episode of Radiation Therapy

Radiation oncology services are generally furnished by a multi-disciplinary team, which consists of the radiation oncologist, radiation oncology nurses, dosimetrists, and a medical physicist. A course of radiation therapy usually includes a clearly defined set of services such as radiation therapy consultation, treatment planning, certain technical preparation and special services, treatment delivery, and treatment management (see Figure 2). The majority of payments are made for treatment delivery services that tend to be highly technical services with minimal physician work.<sup>22, 23</sup>

Consultation	Treatment Planning	Technical Preparation and Special Services	Treatment Delivery	Consultation
<ul style="list-style-type: none"> <li>Initial consultation typically billed using E&amp; M service</li> <li>Example CPT codes; 99201-99205 (E&amp;M outpatient visit)</li> </ul>	<ul style="list-style-type: none"> <li>Determine treatment modality, parts of the body that must be radiated, and plan for radiation treatment</li> <li>Example CPT codes: 77261-77263 (radiation therapy planning)</li> </ul>	<ul style="list-style-type: none"> <li>Technical preparation to ensure radiation dosing is accurate, machine is prepared, treatment aids are constructed</li> <li>Example CPT codes: 77332-77334 (radiation treatment aids)</li> </ul>	<ul style="list-style-type: none"> <li>Radiation delivered to patient in 1 or more sessions</li> <li>Example CPT Codes: 77401-77418 (radiation treatment delivery), 77761-77763 (apply intercavity radiation-brachytherapy)</li> </ul>	<ul style="list-style-type: none"> <li>Patient monitoring, treatment adjusted according to outcomes</li> <li>Example CPT codes: 77427 (radiation treatment management x5 treatments)</li> </ul>

**Figure 2: Services Included in a Radiation Therapy Episode**

The American Society for Radiation Oncology (ASTRO) describes the subcomponents of radiation therapy service in the following manner:<sup>24</sup>

- **Consultation:** A consultation is an E&M service, which typically consists of a medical exam, obtaining a problem-focused medical history, and decision-making about the patient’s

<sup>22</sup> Radiation treatment delivery services paid under the physician fee schedule (e.g., HCPCS code G6016) typically have zero physician work RVUs associated with the service. There are minor exceptions, such as certain brachytherapy treatment delivery services (e.g., CPT codes 77761-77763).

<sup>23</sup> CPT (Current Procedural Terminology) Copyright Notice Throughout this report to Congress, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

<sup>24</sup> American Society for Radiation Oncology (ASTRO). Basics of RO Coding. <https://www.astro.org/Basics-of-Coding.aspx>.

condition/care. Some radiation oncology patients have a consultation, but do not proceed to the stage of treatment planning.

- **Treatment planning:** Treatment planning tasks include determining the disease-bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation—the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process. Treatment planning may involve marking the area to be treated on the patient’s skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.
- **Technical preparation and special services:** Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery, and mathematically determining the dose and duration of radiation therapy. Radiation oncologists frequently work with dosimetrists and medical physicists to perform these services.
- **Radiation treatment delivery services:** Radiation treatment is usually furnished via a form of external beam radiation therapy or brachytherapy, and includes multiple modalities, as discussed in section 4.3 of this report. Although treatment generally occurs daily, the care team and patient determine the specific timing and amount of treatment. The treating physician must verify and document the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.
- **Treatment management:** Radiation treatment management typically includes review of port films, review and changes to dosimetry, dose delivery, treatment parameters, review of patient’s setup, and patient examination. Treatment management also includes follow-up care during the 3 months following completion of external beam radiation therapy.

## **4.5 Medicare Fee-For-Service Payment**

In general, in order for Medicare to pay for furnished items and services, the services must satisfy three basic requirements: (1) they must fall within a statutorily-defined benefit category and not be explicitly excluded from the Medicare benefit; (2) they must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part; and (3) the item or service must not be excluded from Medicare coverage by a local or national coverage determination. Sections 1861(s)(1), (s)(2)(A) and (B), and (s)(4) of the Social Security Act provide for Medicare coverage of radiation therapy and related services. As a result, today Medicare generally covers, as reasonable and necessary, several forms of radiation therapy under both Parts A and B.

Modern radiation therapy is generally furnished in two similar but distinct sites of service: hospital outpatient departments (HOPDs) and freestanding radiation therapy centers (also referred to as “non-facility settings”). HOPDs are paid for technical aspects<sup>25</sup> of radiation therapy services under the Hospital Outpatient Prospective Payment System (OPPS), while freestanding radiation therapy centers are paid for the technical aspects of radiation therapy under the Medicare Physician Fee Schedule (PFS). Medicare Part B pays for the professional services of the radiation oncologist under the PFS, irrespective of where services are furnished. A relatively small volume of radiation therapy services for Medicare inpatients are

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<sup>25</sup> Technical aspects of radiation therapy include most radiation treatment delivery services and many radiation technical preparation and special services. Additional information about these services is in section 4.4 of this report.



paid under the Inpatient Prospective Payment System (IPPS) through the relevant Medical Severity–Diagnosis Related Group (MS-DRG) payment for that hospital stay.

#### **4.5.1 Payments under the Medicare Physician Fee Schedule**

Under the PFS, Medicare Part B pays for services furnished by physicians and certain other practitioners in all sites of service. In addition to physicians, a variety of practitioners, including nurse practitioners, physician assistants, and physical therapists are paid for their professional services through Medicare Part B under the PFS. The services include, but are not limited to, visits, surgical procedures, diagnostic tests, therapy services, and specified preventive services.

Payments under the PFS are based on the relative resources typically used to furnish the service.<sup>26</sup> A service is identified by either a Current Procedural Terminology (CPT<sup>®</sup>) code, which are maintained by the American Medical Association, or a Level II Healthcare Common Procedure Coding System (HCPCS) code, maintained by CMS for programmatic purposes. The relative resources for each code are measured in relative value units (RVUs) for each of three components of a service: (1) professional work, (2) practice expense, and (3) malpractice. The professional work RVU reflects the relative time and intensity associated with furnishing the service. The practice expense RVU includes both indirect expenses such as office space and direct expenses such as the equipment and supplies used in a particular procedure. The malpractice RVU reflects the costs of malpractice insurance. Each of the three RVU components for a service is adjusted to account for geographic variations in the costs of furnishing the service. The product of (1) the sum of the geographically-adjusted RVUs, and (2) the annual PFS conversion factor, equals the PFS payment amount for the service.

The professional services of physicians (and other professionals on the radiation therapy team), such as treatment management, are paid under the PFS regardless of where the radiation therapy is furnished. The technical services associated with radiation therapy delivery in a freestanding radiation therapy center are paid under the PFS, with the practice expense RVUs as the primary determinant of the PFS payment rate for technical radiation therapy services.

Under the PFS, the practice expense RVUs rely heavily on voluntary submission of information, and CMS has few means to validate the accuracy of the submitted information. As a result, CMS previously has indicated that it is difficult to identify consistent and reliable sources of cost information for expensive capital equipment, such as a linear accelerator, to determine accurate practice expense RVUs for physicians' services using such equipment.<sup>27</sup> Further, radiation therapy services and their corresponding codes have been examined under CMS's misvalued codes initiative due to their high growth and use of new technologies.<sup>28</sup> Specifically, CMS reviewed radiation treatment services for Calendar Years (CY) 2009, 2012, 2013, and 2015 as potentially misvalued.<sup>29, 30</sup> CMS has systematically attempted to improve

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<sup>26</sup> Additional background information regarding the PFS is available here: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedcrephysFeeSchedfctsh.pdf>.

<sup>27</sup> 78 FR 43296 / Available here: <https://www.gpo.gov/fdsys/pkg/FR-2013-07-19/pdf/2013-16547.pdf>.

<sup>28</sup> Section 1848(c)(2)(K) of the Social Security Act.

<sup>29</sup> 42 CFR 68919 / 2013 Medicare Physician Fee Schedule Final Rule: <https://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf>.

<sup>30</sup> 42 CFR 67576 / 2015 Medicare Physician Fee Schedule Final Rule: <https://www.gpo.gov/fdsys/pkg/FR-2014-11-13/pdf/2014-26183.pdf>.

the accuracy of pricing for these services under the PFS. PAMPA froze payment rates for 2017 and 2018 and excluded radiation therapy services from the misvalued codes initiative for that same time period.

Although the same code sets generally are used for purposes of the Medicare PFS and OPFS,<sup>31</sup> differences have arisen between the codes used to describe radiation services under the PFS and the OPFS and in commercial use more broadly. CMS continues to use some CMS-specific coding, or HCPCS G-codes, in billing and payment for radiation services.

Through the annual PFS rulemaking process, CMS has received comments from stakeholders representing freestanding radiation therapy centers and physicians who furnish services in those locations about CMS's activities under the misvalued codes initiative, noting the discrepancies and complexity in coding for radiation therapy services. Commenters expressed concerns about differences in payment for freestanding centers and hospital outpatient departments because the fixed, capital costs associated with linear accelerator drive payment amounts do not differ across settings, and noted certain perceived deficiencies in the PFS rate-setting methodology as it applies to treatment services delivered in freestanding radiation therapy centers.<sup>32</sup>

#### **4.5.2 Hospital Outpatient Prospective Payment System**

The Hospital Outpatient Prospective Payment System (OPFS) pays for designated hospital outpatient services; certain Medicare Part B services furnished to hospital inpatients when Part A payment cannot be made; and partial hospitalization services furnished by hospitals or Community Mental Health Centers, among others.<sup>33</sup> Radiation oncology services are included among the covered outpatient services paid for under the OPFS. In the OPFS, individual services described by CPT<sup>®</sup> or Level II HCPCS codes are assigned to payment groups called Ambulatory Payment Classifications (APCs). The payment for each service is based on the APC and is a weighted average of the geometric mean cost of all services assigned to an APC. APC assignments of individual services are based on similar clinical characteristics and similar costs for the procedures assigned to an APC. The payment rate and copayment calculated for an APC apply to each service within the APC. The OPFS radiation therapy APCs are currently organized into two series: levels 1–3 for treatment preparation and levels 1–7 for treatment delivery. Within each of these APC series, the levels proceed from lower to higher cost while maintaining clinical coherence for the services assigned to each of the APCs.

#### **4.5.3 Medicare FFS Incentives and Site-of-Service Payment Differentials**

Under the PFS, a separate code describes each discrete part of the overall radiation treatment. For example, there are separate codes for general radiation therapy planning activities (e.g., CPT<sup>®</sup> codes 77261-77263), planning the specific dosing of radiation therapy (e.g., CPT<sup>®</sup> code 77300) and creating treatment aids that help correctly prepare and position the patient for treatment (e.g., CPT<sup>®</sup> code 77332). Each CPT (or Level II HCPCS) code is associated with a payment rate. Under the OPFS, many individual CPT<sup>®</sup> codes describing radiation therapy services are grouped into APCs based on resource cost and

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<sup>31</sup> Level 1-3 HCPCS codes.

<sup>32</sup> In a call for public comments regarding the development of this report to Congress, stakeholders reiterated the challenges with the fluctuations in payments under the PFS and asked for more price stability in the development of a potential model. See section of this report 8 for further discussion.

<sup>33</sup> Additional background information regarding the OPFS is available here: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsh.pdf>.



clinical similarity, and all codes within an APC have the same payment rate. However, radiation therapy services have typically not been grouped into APCs with codes from different components<sup>34</sup> of the broader radiation therapy episode. For example, radiation treatment delivery codes are not grouped into APCs with radiation treatment planning codes. A hospital outpatient encounter can involve multiple services that are assigned to multiple APCs and most radiation services can be paid separately in an OPD.<sup>35</sup> Since CMS typically pays for radiation services separately and on a per service basis (in both the PFS and OPDS), the more radiation services furnished by a clinician or hospital outpatient department, the more claims that a clinician or hospital outpatient department submits to Medicare.

Because the OPDS and PFS are resource-based payment systems, higher payment rates are typically assigned to services that use more expensive equipment. Researchers have indicated those resource-based payments may encourage health care providers to purchase and furnish higher-cost services, if they have a sufficient volume of patients to cover their fixed costs.<sup>36</sup> Higher payment rates for services involving certain treatment modalities may encourage use of those modalities over others.<sup>37</sup>

As noted previously in this report to Congress, research has shown that from 2000 to 2010, Medicare Part B spending on radiation therapy increased 216% due primarily to the adoption and uptake of IMRT.<sup>38</sup> The Government Accountability Office (GAO) examined Medicare self-referral trends among radiation oncology services and its findings suggest that financial incentives for self-referring physicians, particularly those in limited specialty groups<sup>39</sup>, were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT.<sup>40</sup>

Because there are differences in the underlying methodologies used in the OPDS and PFS for rate setting, there often are differences in the payment rate for the same radiation therapy service depending on whether the service is furnished in a freestanding radiation therapy center paid under the PFS, or a hospital outpatient department paid under the OPDS. This is called the site-of-service payment differential, and stakeholders from freestanding radiation therapy centers have asserted that such differentials between hospital outpatient departments and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting.

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<sup>34</sup> These components are discussed further in section 4.5 of this report.

<sup>35</sup> Most radiation therapy services are not subject to OPDS packaged payment policies. There are small exceptions. For example, beginning in 2015, a comprehensive APC was established for Stereotactic Radio Surgery (SRS) services, meaning certain items and services furnished with SRS services are packaged with the primary OPDS payment for the SRS service.

<sup>36</sup> Falit, B. P., Chernew, M. E., & Mantz, C. A. (2014). Design and implementation of bundled payment systems for cancer care and radiation therapy. *International Journal of Radiation Oncology• Biology• Physics*, 89(5), 950-953.

<sup>37</sup> Ibid.

<sup>38</sup> Shen, X., Showalter, T. N., Mishra, M. V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. *Journal of Oncology Practice*, 10(4), e201-e207.

<sup>39</sup> The GAO defined physician groups as "limited specialty" if more than 75 percent of its office visits were performed by urologists, non-physician practitioners (e.g., physician assistants), or providers whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists.

<sup>40</sup> Higher Use of Costly Prostate Cancer Treatment By Providers Who Self-Refer Warrants Scrutiny, GAO 13-525. July 2013. U.S. Government Accountability Office Report to Congressional Requesters.

## **5. Review of CMS Episodic Alternative Payment Models**

Episodic payments (also called “bundled payments”) are an alternative payment method in which the payer sets a single spending target for all applicable health care services furnished during a clinical episode of care over a specified period. The CMS Innovation Center is testing several episode payment models, including the Oncology Care Model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative. These models test whether episode payments reduce program expenditures while preserving or enhancing the quality of care furnished to individuals in the Medicare program.

### **5.1 Oncology Care Model**

The Oncology Care Model aims to provide higher-quality, more highly coordinated oncology care at the same or lower cost to Medicare.<sup>41</sup> The CMS Innovation Center launched the OCM on July 1, 2016 with nearly 200 physician practices and 16 health plans. The performance period of the model will run for 5 years. The CMS Innovation Center designed the model in consultation with stakeholders from the medical, consumer, and business communities who believed an alternative payment model for oncology care would better support beneficiaries and clinicians’ work with their patients.

OCM incentivizes participating physician group practices to comprehensively and appropriately address the complex care needs of Medicare beneficiaries receiving chemotherapy treatment, and heightens the focus on furnishing services that improve the patient experience and/or health outcomes.

OCM episodes of care span 6 months following the initiation of chemotherapy treatment for cancer. OCM incorporates a two-part payment system for participating practices. The first is a monthly per-beneficiary-per-month (PBPM) payment that the practice may be eligible to be paid throughout the duration of an episode, referred to as the Monthly Enhanced Oncology Services (MEOS) Payment. The \$160 MEOS Payment helps pay for the OCM practices’ costs related to increased care coordination and access to care for Medicare FFS beneficiaries receiving chemotherapy services. The second part of the payment system is a performance-based payment that practices may be eligible to receive if they lower the total cost of care, while delivering high-quality care for beneficiaries during the episode.

To calculate the performance-based payment, all Medicare Part A and Part B expenditures as well as certain Part D expenditures during the episode are included in the total cost of care, which will be compared against a target price (calculated as a risk-adjusted benchmark reduced by the applicable discount) for all episodes attributed to the practice. This amount is then adjusted based on the practice’s achievement on the Oncology Care Model Quality Measures.

The OCM evaluation will assess the effects of the model on quality of care and costs, including whether the model achieves better health, better health care, and lower Medicare per capita costs for OCM beneficiaries. The evaluation will seek to understand what aspects of the model contribute most to success and how contextual factors influence this success. Employing a mixed-methods approach, the evaluation will include rigorous qualitative and quantitative analyses to answer questions about OCM’s implementation effectiveness; impact on quality of care, health outcomes, utilization, and costs; and generate lessons learned regarding stakeholder engagement and scalability. Major primary data collection activities may include practice site visits, surveys, and stakeholder interviews and focus groups.

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<sup>41</sup> The Oncology Care Model. Available at: <https://innovation.cms.gov/initiatives/Oncology-Care/>.

Additional data sources will include Medicare FFS claims data and practices' clinical and quality measure reporting.

## **5.2 Bundled Payments for Care Improvement**

The BPCI initiative comprises four broadly defined models of care that link payments for the multiple services furnished to beneficiaries during an episode of care.<sup>42</sup> In the BPCI models, episodes of care are triggered by an inpatient stay in an acute care hospital. Participating organizations (Awardees) enter into model participation agreements with CMS that include financial and performance accountability for episodes of care. BPCI participants had the opportunity to choose participation in one or more clinical episodes, representing a range of surgical and medical episodes.

In Model 1, the episode of care was defined as the inpatient stay in the acute care hospital. Medicare paid the hospital a discounted amount based on the payment rates established under the Inpatient Prospective Payment System used in the original Medicare program. Medicare continued to pay physicians separately for their services under the Medicare Physician Fee Schedule. BPCI Model 1 concluded at the end of Calendar Year (CY) 2016.

Models 2 and 3 involve a retrospective bundled payment arrangement where actual expenditures are reconciled against a target price for an episode of care. In Model 2, the episode includes the inpatient stay in an acute care hospital plus the post-acute care and all related services up to 90 days after hospital discharge. In Model 3, the episode of care is triggered by an acute care hospital stay, but begins at the initiation of post-acute care services with a skilled nursing facility, inpatient rehabilitation facility, long term care hospital, or home health agency, and continues for up to 90 days. Under Models 2 and 3, Medicare continues to make FFS payments to providers and suppliers participating in the model. After comparing aggregate expenditures to the target price for the episode, Medicare either makes an additional payment to or recoups amounts owed from the Awardee.

In Model 4, CMS makes a single, prospectively determined bundled payment to the hospital Awardee that encompasses all services furnished by the hospital, physicians, and other practitioners during the episode of care that lasts the entire inpatient stay. Physicians and other practitioners submit "no-pay" claims to Medicare and are paid by the hospital out of the bundled payment, unless they choose to opt out of the model payment methodology.

The implementation of Models 2, 3, and 4 was divided into two phases. During Phase 1, also referred to as "the preparation period," CMS shared data and engaged in education and shared learning activities with participants as they prepared to assume financial risk under Phase 2, the performance, or "risk-bearing," period. In BPCI, the Awardee is the entity that enters into the model participation agreement with CMS and assumes financial liability for the episode spending. Episode Initiators are health care providers who trigger BPCI episodes of care; these providers may be an Awardee, and bear risk directly, or participate in BPCI through an Awardee Convener. BPCI Episode Initiators include acute care hospitals, skilled nursing facilities, physician group practices, home health agencies, inpatient rehabilitation facilities, and long term care hospitals that trigger an episode of care.

CMS announced the first set of Phase 1 participants for BPCI Models 2, 3, and 4 in January 2013. By October 2013, some BPCI participants signed Awardee Agreements with CMS, and began bearing

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<sup>42</sup> Bundled Payments for Care Improvement (BPCI) Initiative: General Information is available at: <https://innovation.cms.gov/initiatives/bundled-payments/>.

financial risk for some or all of their episodes. CMS required all participants to transition at least one episode into Phase 2 by July 2015 as a condition of continued participation in the initiative. Awardees were required to transition any remaining episodes into Phase 2 by October 2015.

As of July 1, 2017, BPCI has 1,244 participants in Phase 2, consisting of 261 Awardees and 983 Episode Initiators actively involved in care redesign.

The CMS Innovation Center released the 2014 annual report for Model 1<sup>43</sup> on July 9, 2015. That report evaluated the participation of 24 Model 1 Awardees. Impact estimates indicated that Medicare payment increases were muted, increasing less than comparisons for Awardees over the primary period of focus under this model, the inpatient stay (episode). Medicare payments to other health care providers after the episode period, such as physicians, nursing facilities, and rehabilitation hospitals, increased relative to baseline and comparison hospitals. The 2015 annual report for Model 1<sup>44</sup> was released on May 18, 2016. That report evaluated the participation of the 24 Model 1 Awardees—including 13 Awardees that terminated their participation in the model prior to November 1, 2015. Analysis of the first two years of the model showed that Medicare payments found no consistent negative or positive statistically significant impacts. Additionally, there were no consistent negative or positive impacts on claims-based health outcomes. These Medicare payment findings provide interim insights on potential Model 1 effects.

The CMS Innovation Center released the second annual evaluation report for BPCI Models 2, 3, and 4<sup>45</sup> on September 19, 2016. The evaluation used Medicare claims data from the first year of the initiative. Future evaluation reports will have greater ability to detect changes in payment and quality due to larger sample sizes and the recent rapid growth in participation of the initiative, which are not reflected in current findings. Key highlights include:

- BPCI-participating health care providers tend to be larger entities, operate in more affluent urban areas, have higher episode costs, and differ in other ways from health care providers who did not participate. Many indicated that commitment from their leadership and financial investment in consultants or other resources were key factors to implement BPCI changes.
- Of the 15 clinical episode groups analyzed, 11 showed potential savings to Medicare. Future evaluation reports will have more data to analyze individual clinical episodes within these and additional groups.
- Orthopedic surgery under Model 2 hospitals showed statistically significant savings of \$864 per episode. This was because of reduced use of institutional post-acute care (i.e., skilled nursing facility and inpatient rehabilitation facility) following the hospitalization. In addition to diminished cost, beneficiary surveys of orthopedic surgery episodes under Model 2 also indicated improved quality. Beneficiaries who received their care at participating hospitals indicated that they had greater improvement after 90 days post-discharge in two mobility measures than beneficiaries from comparison hospitals.
- Cardiovascular surgery episodes under Model 2 hospitals have not shown any savings yet, but quality of care has been preserved. Over the next year, the CMS Innovation Center will have

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<sup>43</sup> [https://downloads.cms.gov/files/cmimi/BPCIM1\\_ARY1\\_Report.pdf](https://downloads.cms.gov/files/cmimi/BPCIM1_ARY1_Report.pdf).

<sup>44</sup> <https://innovation.cms.gov/Files/reports/bpci-mdl1yr2annrpt.pdf>.

<sup>45</sup> <https://innovation.cms.gov/Files/reports/bpci-models2-4-yr2evalrpt.pdf>.

significantly more data available, enabling the agency to better estimate effects on costs and quality.

Building on the BPCI initiative, the CMS Innovation Center intends to implement a new bundled payment model for CY 2018 that would be designed to meet the criteria for an Advanced APM.<sup>46</sup>

## **6. Private Sector Initiatives**

There have been a few private sector initiatives to bundle payments for radiation oncology services, although radiation oncology bundles have developed more slowly than general oncology bundles.<sup>47</sup>

The most relevant private sector initiative was a prospective episodic payment created by 21st Century Oncology and Humana Inc. This pilot is the only private initiative on radiation oncology for which published results are available. Under its agreement, 21st Century Oncology has negotiated bundled payments for radiation therapy for 13 common diagnoses, including breast, lung, and prostate cancers.<sup>48</sup> Payment does not change based on the number of treatments, certain patient risk factors, or patient comorbidities.<sup>49</sup> A representative from 21<sup>st</sup> Century Oncology shared model design and current results at the CMS public listening session discussed in section 8.1 of this report.

Two additional radiation therapy bundled payment initiatives include Roswell Park Cancer Institute and Valley Radiotherapy, although there is much less publicly available information regarding their details and outcomes. In 2012, Roswell Park Cancer Institute contracted with three insurers to accept bundled payments for breast cancer radiation therapy. In July 2016, Anthem Blue Cross of California and Valley Radiotherapy Associated announced that they will implement new bundled payment rates for breast cancer patients, beginning in May 2017.<sup>50</sup>

## **7. Episodic Alternative Payment Model: Design Considerations**

### **7.1 Key Design Elements**

CMS has outlined certain key elements to consider in designing alternative payment models.<sup>51</sup> The key elements include the following:

1. Type of Alternative Payment Model(s)
2. How Model Will Result in Clinical Practice Transformation
3. Rationale for Alternative Payment Model
4. Scale of Alternative Payment Model

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<sup>46</sup> Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) 82 Fed. Reg. at 216, (Jan. 3, 2017).

<sup>47</sup> Falit, B. P., Chernew, M. E., & Mantz, C. A. (2014). Design and Implementation of Bundled Payment Systems for Cancer Care and Radiation Therapy. *International Journal of Radiation Oncology• Biology• Physics*, 89(5), 950-953.

<sup>48</sup> Ibid.

<sup>49</sup> Ibid.

<sup>50</sup> <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2016/anthem-blue-cross-of-california-and-valley-radiotherapy-associates-implement-new-rates-for-patients/>.

<sup>51</sup> [https://qpp.cms.gov/docs/QPP\\_How\\_to\\_Design\\_an\\_APM.pdf](https://qpp.cms.gov/docs/QPP_How_to_Design_an_APM.pdf).

5. Alignment with Other Payers and CMS Programs
6. Measurement of Improved Clinical Quality and Patient Experience of Care
7. Ease of Participant Implementation

The following sections present a description and analysis of each element relative to a potential episodic alternative payment model for radiation therapy services.

### **7.1.1 Element 1 – Type of Alternative Payment Model**

An APM (defined below) is a payment approach that gives added incentive payments to participants that provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. The Quality Payment Program, which was established to implement provisions of the MACRA, specifies two categories of APMs: Alternative Payment Models and Advanced Alternative Payment Models (Advanced APMs). As defined by MACRA, all models tested under the CMS Innovation Center’s statutory authority are by definition APMs, except for Health Care Innovation Awards. See Table 4 below for the complete MACRA definition of APMs.

An episodic APM for radiation therapy services furnished in freestanding settings could be an APM and/or an Advanced APM. APMs can allow participants to potentially earn more for taking on some risk related to their patients’ outcomes. Radiation therapy stakeholders have expressed interest in the development of an Advanced APM as referenced in section 8.3. Advanced APMs are those that meet certain statutory and regulatory criteria for financial risk, use of certified electronic health record technology, and payment based on Merit-based Incentive Payment System (MIPS)-comparable quality measures. In addition to performance incentives within the APM, participants in Advanced APMs may earn a 5% incentive payment through the Quality Payment Program for payment years from 2019 through 2024 by achieving threshold levels of payments or patients through the Advanced APM. To qualify as an Advanced APM, a potential radiation therapy episode model must meet the following criteria:

1. Require participants to use Certified Electronic Health Record Technology (CEHRT);
2. Payment for covered professional services must be based on quality measures comparable to those in MIPS; and,
3. Require participants to bear more than nominal risk, or be a Medical Home Model expanded under section 1115A(c) of the Act (the CMS Innovation Center’s authority to expand a model test).

**Table 4: Types of Alternative Payment Models as Defined under the Quality Payment Program**

<b>Alternative Payment Model (APM)</b>	<b>Advanced Alternative Payment Model (Advanced APM)</b>
<ul style="list-style-type: none"> <li>• CMS Innovation Center Models<sup>52</sup> (other than a Health Care Innovation Award); or</li> <li>• The Medicare Shared Savings Program; or</li> <li>• Demonstration under the Health Care Quality Demonstration Program authority; or</li> <li>• Demonstration required under federal law</li> </ul>	<ul style="list-style-type: none"> <li>• Is an APM; and</li> <li>• Requires Participants to Use Certified EHR Technology; and</li> <li>• Bases payment for covered professional services on quality measures comparable to those in MIPS; and</li> <li>• Participants bear more than nominal financial risk, or APM is a Medical Home Model expanded under Innovation Center authority</li> </ul>

<sup>52</sup> Those CMS Innovation Center Models implemented under section 1115A of the Act.



## **7.1.2 Element 2 – How Model Will Result in Clinical Practice Transformation**

A potential episode payment model for radiation therapy may transform clinical practice by incentivizing greater adherence to clinical guidelines, reducing administrative burden, and allowing physicians to provide more patient-centric high value care (paying for value, rather than volume), i.e., incentivizing quality improvement through linking payment to quality of care.

### **7.1.2.1 Adherence to Clinical Guidelines**

Several organizations publish clinical guidelines on radiation therapy services. These guidelines are often developed through a multi-disciplinary consensus-based process. Organizations that publish clinical radiation therapy guidelines include the National Comprehensive Cancer Network, American Society for Radiation Oncology, and American College of Radiology. Adherence to clinical guidelines could decrease variation in practice patterns and increase the quality of care.

An episode payment model for radiation therapy services could incentivize the use of clinical guidelines in several ways. These could include making either use of, or consideration of clinical guidelines, a requirement of the model, recognizing that treatment according to guidelines may not always be clinically appropriate. For example, the CMS Innovation Center's OCM requires participating practices to consult and use nationally recognized clinical guidelines; however, the model allows practices to provide explanations for treatment decisions not in accordance with these guidelines. Such explanations must be documented in the OCM beneficiary's Electronic Health Record. Adherence to clinical guidelines may also be measured and rewarded through use of standardized, evidence-based, and well-tested clinical quality measures, or monitored through claims data and/or site visits. The following sections address these issues in more detail.

### **7.1.2.2 Reducing Administrative Burden**

As noted in prior sections of this report, Medicare currently pays for most radiation therapy through two payment systems—the Medicare Physician Fee Schedule and the Hospital Outpatient Prospective Payment System.<sup>53</sup> Although the codes used in these payment systems are generally the same for most services, many of the codes for radiation therapy are different across payment systems, even when they describe the same service.<sup>54</sup> This may create complexity for hospitals and physicians, especially those that practice in multiple settings. A potential model could test a different approach to the two coding and payment systems.

### **7.1.2.3 Paying for Value Rather than Volume**

An episode payment model for radiation therapy services could incentivize physicians to furnish more high-value, patient-centric care. Radiation therapy furnished in the freestanding and outpatient hospital settings have historically been paid on a per-service basis through the PFS or the Hospital OPFS, respectively. Under the current FFS system, some stakeholders have indicated there may be a financial incentive to provide more technically complex services. Both incentives may generate higher Medicare

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<sup>53</sup> Additional information about these payment systems is available in section 4.5 of this report.

<sup>54</sup> For example, the codes used to describe most external beam therapies, such as conventional external beam therapy and IMRT, are different across the two payment systems. The Physician Fee Schedule uses codes G6001 – G6017 while the Hospital Outpatient Prospective Payment System uses codes 77402, 77407, 77412, 77385, 77386 (among others) to describe the same services.

expenditures. An episode payment model offers the opportunity to shift incentives to focus on higher quality, more cost-effective care.

A potential model could also test more stable pricing for freestanding radiation therapy centers paid under the Medicare Physician Fee Schedule. As previously discussed in section 4.5.1, CMS faces certain challenges in determining accurate prices for services that involve expensive capital equipment. Consequently, PFS rates for services involving external beam radiation have fluctuated over the last decade. Under an episode payment model, more stable prices for radiation therapy services could be tested to determine if they reduce expenditures while maintaining or enhancing quality of care.

#### **7.1.2.4 Participation in Peer-to-Peer Learning Network**

Physicians participating in a potential model could have an opportunity to participate in a peer-to-peer learning network. Other CMS Innovation Center models, including the OCM and Comprehensive Primary Care Plus, provide opportunities for participants to work collaboratively on performance improvement. This may range from participant shared communication platforms and educational webinars on specific topics of interest, to small action groups, organized around participants who are focused on solving a specific problem. These opportunities enable participants to learn from their peer network and share best practices.

As part of the episode payment model, CMS could also create a small-scale data registry to collect basic clinical information on beneficiaries treated by model participants. This basic clinical information is typically not available in Medicare claims. For example, information regarding the stage of the cancer and the intent of treatment – i.e., whether radiation is being used as a primary curative therapy or for palliative care – is not readily available in Medicare claims. This clinical information could support monitoring and practice benchmarking that could be shared among model participants, and help refine the model in the future to adjust for certain patient characteristics.

#### **7.1.3 Element 3 – Rationale for Alternative Payment Model**

A potential radiation therapy model could allow for testing of different forms of Medicare payment and which may spur different decisions around the type of radiation furnished (modality), the total amount of radiation given (the dose), and how that radiation is divided up (the number of fractions).

Radiation treatment can be furnished in different forms and in both freestanding radiation therapy centers and hospital outpatient departments depending on the equipment available. These include external beam radiation therapy, brachytherapy, and infused radiopharmaceuticals. As discussed in section 4.3, there are several types of external beam radiation therapy. As shown in Table 5, Medicare payment varies by modality and there is heterogeneity in the use of modality.



**Table 5: Analysis of all 90-Day Episodes January 1, 2013 – December 31, 2015 by Type of Radiation**

Treatment Type	Conventional External Beam <sup>55</sup>	Brachytherapy	Proton Beam	Stereotactic Radio Surgery	IMRT
Percent of Episodes	53%	5%	1%	9%	32%
Average Episode Cost (Medicare Expenditures <sup>56</sup> )	\$6,970	\$10,200	\$30,541	\$10,264	\$18,750

For external beam radiation, the total radiation dose is typically split into daily fractions (i.e., the total radiation amount is divided into multiple treatments, which are known as fractions). Because Medicare pays on a per-fraction basis, there is an incentive to furnish more, rather than fewer, fractions.

For some cancer types, stages and characteristics, a shorter course of treatment with more radiation per fraction may be appropriate. Several randomized controlled trials have shown that shorter treatment schedules for low-risk breast cancer yield similar cancer control and cosmetic outcomes.<sup>57, 58, 59, 60</sup> Furthermore, research has shown that radiation oncologists consistently split treatment for bone metastases into 5 to 10 fractions, although some research indicates one treatment is often sufficient.<sup>61, 62, 63, 64</sup> Some have speculated that this may be partly due to the financial incentives currently embedded in Medicare payment, as discussed in section 4.5.3 of this report. Modifying payment under an episode payment model could change the incentives and encourage physicians to pick higher-value modalities and furnish fewer fractions, where appropriate.

### 7.1.4 Element 4 – Scale of Alternative Payment Model

Alternative payment models can be larger (include more participants, beneficiaries, payments and services, etc.) or smaller (include fewer participants, beneficiaries, payments, services) depending on the

<sup>55</sup> Conventional External Beam radiation therapy included Image-Guided Radiation Therapy and 3-D Conformal Radiation Therapy.

<sup>56</sup> These figures only represent Medicare expenditures and do not include, for example, co-insurance payments made by the beneficiary. Beneficiaries are typically responsible for 20% of Medicare Part B services.

<sup>57</sup> Whelan, T.J. et al. Long-term Results of Hypofractionated Radiation Therapy for Breast Cancer. *N. Engl. J. Med.* 2010 Feb. 11; 362(6):513-20. <https://www.ncbi.nlm.nih.gov/pubmed/20147717>.

<sup>58</sup> Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial A of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. *Lancet Oncol.* 2008 Apr.; 9(4):331-41. <https://www.ncbi.nlm.nih.gov/pubmed/18356109>.

<sup>59</sup> Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial B of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. *Lancet Oncol.* 2008 Mar. 29; 371(9618): 1098-107. <https://www.ncbi.nlm.nih.gov/pubmed/18355913>.

<sup>60</sup> Haviland, J.S. et al. The UK Standardisation of Breast Radiotherapy (START) Trials of Radiotherapy Hypofractionation for Treatment Of Early Breast Cancer: 10-Year Follow-Up Results of Two Randomised Controlled Trials. *Lancet Oncol.* 2013 Oct.; 14(11): 1086-94. <https://www.ncbi.nlm.nih.gov/pubmed/24055415>.

<sup>61</sup> Sze, W.M. et al. Palliation of Metastatic Bone Pain: Single Fraction Versus Multifraction Radiotherapy – A Systematic Review of The Randomised Trials. *Cochrane Database Syst. Rev.* 2004; (2):CD004721. <https://www.ncbi.nlm.nih.gov/pubmed/15106258>.

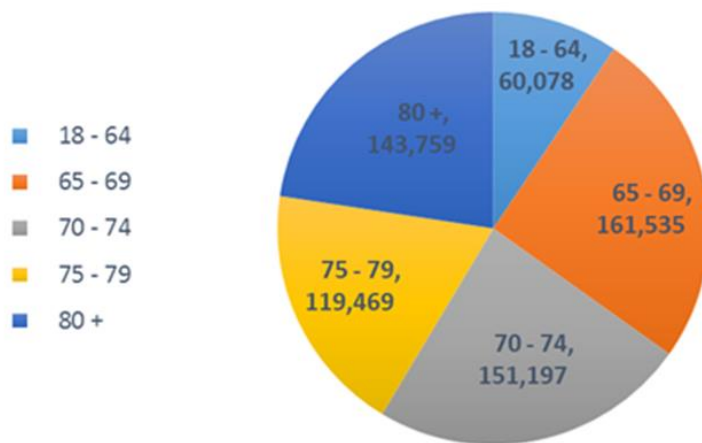
<sup>62</sup> Chow, E. et al. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. *Clin. Oncol. (R. Coll. Radiol.)*. 2012 Mar;24 (2):112-24. <https://www.ncbi.nlm.nih.gov/pubmed/22130630>.

<sup>63</sup> Chow, Ronald et al. Efficacy of Multiple Fraction Conventional Radiation Therapy for Painful Uncomplicated Bone Metastases: A Systematic Review. *Radiotherapy & Oncology: March 2017 Volume 122, Issue 3, Pages 323-331.* [http://www.thegreenjournal.com/article/S0167-8140\(16\)34483-8/abstract](http://www.thegreenjournal.com/article/S0167-8140(16)34483-8/abstract).

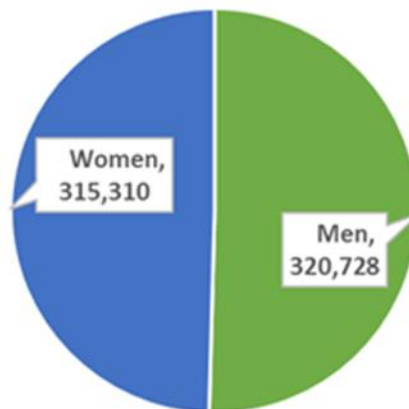
<sup>64</sup> Lutz, Stephen et al. Palliative Radiation Therapy for Bone Metastases: Update of an ASTRO Evidence-Based Guideline. *Practical Radiation Oncology* (2017) 7, 4-12. [http://www.practicalradonc.org/article/S1879-8500\(16\)30122-9/pdf](http://www.practicalradonc.org/article/S1879-8500(16)30122-9/pdf).

needs of the model test and to ensure that the intervention is large enough to produce reliable results and allow for meaningful evaluation. Because radiation is a widespread treatment for cancer (and certain other conditions), the scale and scope of a potential episode payment model for radiation could be determined based on the specific aims of the model and its design.

Many Medicare beneficiaries are treated with radiation for their diagnoses. Based on CMS’s analysis of Medicare claims, between January 1, 2013 and December 31, 2015, 591,298 unique Medicare beneficiaries had an episode of radiation to treat cancer. There were 636,040 total episodes during that period, as some Medicare beneficiaries had more than one episode of radiation during the 3-year period. Figures 3 and 4 present information on the demographics of beneficiaries that had episodes of radiation. Of note, a smaller percentage (9%) of episodes were to treat beneficiaries between the ages of 18 and 64, as compared to those episodes to treat beneficiaries 65 and older. In addition, across all episodes, there were roughly the same number of men and women.



**Figure 3: Demographics of All Episodes of Radiation January 1, 2013 – December 31, 2015: Age of Medicare Beneficiaries**



**Figure 4: Demographics of All Episodes of Radiation January 1, 2013 – December 31, 2015: Sex of Medicare Beneficiaries**

The scope of a potential APM on radiation therapy would depend on the settings of care (and their corresponding payment systems) included in the model. Section 3(b) of the PAMPA directed the Secretary to “submit to Congress a report on the development of an episodic alternative payment model...for radiation therapy services furnished in nonfacility settings.” A model that only included freestanding radiation therapy centers would exclude radiation furnished in hospital outpatient

departments. Such a model would exclude a significant amount of radiation care furnished to Medicare beneficiaries. Based on CMS's analysis of Medicare claims (previously discussed in section 4.1 of this report), in roughly 62% of episodes of radiation treatment provided between January 1, 2013 and December 31, 2015, a hospital outpatient department furnished the majority of the radiation treatment delivery services. In 38% of the episodes, a freestanding radiation therapy center furnished the majority of the treatment delivery services. Section 4.3 provides a description of radiation treatment delivery services and the activities where radiation is furnished to the patient. Of the services included in an episode of radiation, treatment delivery services are typically the greatest source of Medicare spending.

Radiation oncologists provide radiation therapy in both freestanding radiation therapy centers and outpatient hospital departments. The American Society for Radiation Oncology estimates that there are 5,000 radiation oncologists in the US.<sup>65</sup> Using claims associated with all of the episodes of radiation between January 1, 2013 and December 31, 2015, CMS identified 4,749 unique physicians who self-identified as a radiation oncologist and furnished care to the beneficiary during the 90-day episode.<sup>66</sup> The numerical difference between CMS's analysis and ASTRO's projected number of radiation oncologists could be because certain radiation oncologists may be employed in capacities other than clinical care (e.g., teaching, research) and some radiation oncologists may not treat Medicare patients.

### **7.1.5 Element 5 – Alignment with Other CMS Programs**

As noted in other sections of this report, the CMS Innovation Center is testing an Oncology Care Model that focuses on Medicare beneficiaries with cancer who are undergoing chemotherapy. Under the OCM, physician practices may be eligible to receive performance-based payments for episodes of care surrounding chemotherapy administration to cancer patients. Alignment between the OCM and a potential episode payment model for radiation oncology is particularly important because a significant number of beneficiaries who receive chemotherapy also receive radiation. For specific types of cancer, such as certain forms of advanced lung and head and neck cancers, chemotherapy and radiation are both part of the standard course of treatment. Based on our analysis of Medicare beneficiaries that received radiation between January 1, 2013 and December 31, 2015, roughly 31% of beneficiaries who received radiation during that time received a type of chemotherapy 30 days before or 90 days after initiating radiation.

While radiation therapy is not on the list of therapies that can trigger an episode under OCM, in determining whether a participating practice is eligible to receive a performance-based payment, the costs of radiation therapy services furnished to an OCM beneficiary within 6 months of a triggering chemotherapy service are included when reconciling the total cost of care during an episode against a pre-determined episode Target Price. In addition, receipt of radiation services is also used for purposes of risk adjusting the Baseline Price used to calculate that Target Price. Also, a radiation therapy schedule, as applicable, is also a required component of the initial care plan that a participating practice must certify to providing as a condition of participating in the model.

The alignment between a potential model on radiation therapy and the OCM would depend on the design and specific goals of the radiation therapy model. For example, OCM could be modified to incorporate additional radiation therapy components by broadening the types of beneficiaries and episodes included in OCM. The approach could maintain the basic OCM payment and episode attribution structure, but

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<sup>65</sup> ASTRO 2015 Legislative Priorities. Retrieved from [https://www.astro.org/uploadedFiles/Main\\_Site/Meetings\\_and\\_Events/2015\\_Advocacy\\_Day/Advocacy%20Day%20-%20iPad%20-%20\(Linked\).pdf](https://www.astro.org/uploadedFiles/Main_Site/Meetings_and_Events/2015_Advocacy_Day/Advocacy%20Day%20-%20iPad%20-%20(Linked).pdf).

<sup>66</sup> Medicare FFS claims include a data field for "physician specialty". Code "92" is used to represent "radiation oncologist." "Unique physicians" were identified through unique National Provider Identifiers (NPIs).

include radiation therapy as an episode trigger under the model. An alternative approach would be to develop a potential radiation therapy model that is separate and apart from OCM with a potentially different payment model, attribution methodology, participation requirements, and practice transformation requirements (among other features) from those tested under OCM. Under either approach (or other potential options not considered here), the CMS Innovation Center would closely review how to calculate Medicare savings across these two models (as well as across other CMS initiatives) and how to allow cross-participation without compromising the model tests.

In addition to OCM, there is potential for overlap with other CMS Innovation Center models and other initiatives, including accountable care organization (ACO) initiatives and other episode payment models. In developing the radiation therapy episode, as part of the radiation therapy episode payment model design, CMS would need to consider several potential issues related to potential overlap, including:

- Whether participants in the radiation oncology episode may also participate in other (initiatives and, if so, which initiatives; and
- How beneficiary/episode overlap between initiatives may be handled, including handling any performance-based payment to ensure that CMS does not pay twice for the same reduction in expenditures?

### **7.1.6 Element 6 – Measurement of Improved Clinical Quality and Patient Experience of Care**

Measures of quality and patient experience are used to track clinical performance, focus model participants on specific clinical areas, and drive improvement in clinical outcomes and patient experience. Many CMS Innovation Center models, including the Oncology Care Model, the Comprehensive Care for Joint Replacement Model,<sup>67</sup> Comprehensive Primary Care Plus,<sup>68</sup> and the Next Generation ACO Model,<sup>69</sup> require participants to report measures of quality and/or patient experience. Those models also tie certain model payments to quality. For example, whether an OCM practice is eligible to receive a Performance-Based Payment depends on the practice’s performance on quality and patient experience measures.

The CMS Innovation Center was established by section 1115A of the Social Security Act. Congress created the Innovation Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or Children’s Health Insurance Program (CHIP) benefits. The CMS Innovation Center statute requires quality of care to be “preserved or enhanced,” and requires that the CMS Innovation Center conduct an evaluation of all models tested by the Center. These evaluations must include an analysis of quality of care, “including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.”

In addition, Section 1833(z)(3)(D) of the Act (as added by MACRA), requires that, among other criteria, to be considered an Advanced APM, the APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS. In other words, if participants are not required to report quality measures in a potential model on radiation therapy, then the model would not be considered an “Advanced APM” and model participants would not be eligible for the 5% incentive payment (based on their participation in the model).

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<sup>67</sup> <https://innovation.cms.gov/initiatives/cjr>.

<sup>68</sup> <https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus/index.html>.

<sup>69</sup> <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/>.

The following criteria could serve as a possible guide for measure selection under a potential model on radiation therapy. These criteria reflect key factors used for the selection of measures used in other CMS quality programs such as the Quality Payment Program and the criteria used by the National Quality Forum (NQF) for the endorsement of measures. The criteria are:

- **Burden and alignment:** Minimize undue reporting burden for participants by leveraging existing reporting processes and existing quality measures that are already in use in other CMS quality reporting programs such as MIPS.
- **Rigor:** Prioritize measures that have been endorsed by a consensus-based entity or those measures that have a strong evidence-based focus and tested for reliability and validity.
- **Model test:** Focus on measures that provide insight into the model test and understanding how effective the model is to facilitate achievement of the model's aims.
- **Harmonization:** Support comparisons of quality across episode bundles and other CMS model tests by prioritizing the selection of cross-cutting measures, such as NQF # 419: Documentation of Medications in the Medical Record.

Based on these criteria, CMS reviewed measures in the Merit-based Incentive Payment System, measures used by relevant specialty societies, measures used in the Oncology Care Model and measures used in other CMS programs (e.g., the PPS-Exempt Cancer Hospital Quality Report Program).

Table 6 lists examples of quality and patient experience measures that may be relevant for a potential model on radiation oncology. One of the three criteria to be an Advanced APM is that the APM must include measures tied to payment that are comparable to those in MIPS. All but one of the measures in the list in Table 6 are included in the MIPS list of measures for performance year 2017.<sup>70</sup> In addition, all but one of the measures identified below are endorsed by the NQF. The NQF criteria for measure endorsement, which align with the criteria above, are that the measures must be:

- **Important to measure** and report to keep our focus on priority areas, where the evidence is highest that measurement can have a positive impact on healthcare quality.
- **Scientifically acceptable**, so that the measure when implemented will produce consistent (reliable) and credible (valid) results about the quality of care.
- **Useable and relevant** to ensure that intended users—consumers, purchasers, providers, and policy makers—can understand the results of the measure and are likely to find them useful for quality improvement and decision-making.
- **Feasible to collect** with data that can be readily available for measurement and retrievable without undue burden.<sup>71</sup>

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<sup>70</sup> This list of measures is available here: <https://qpp.cms.gov/mips/quality-measures>

<sup>71</sup> [https://www.qualityforum.org/Measuring\\_Performance/ABCs/What\\_NQF\\_Endorsement\\_Means.aspx](https://www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx)



**Table 6: Examples of Quality Measures that Pertain to Radiation Oncology**

Measure Name	Measure Type	Measure Steward	NQF Number	In MIPS
Oncology: Radiation Dose Limits to Normal Tissue	Process	American Society for Radiation Oncology	382	Yes
Oncology: Medical and Radiation – Plan of Care for Pain	Process	American Society of Clinical Oncology	383	Yes
Oncology: Medical and Radiation – Pain Intensity Quantified	Process	Physician Consortium for Performance Improvement	384	Yes
Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Process	Physician Consortium for Performance Improvement	389	Yes
Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Process	Centers for Medicare & Medicaid Services	418	Yes
Documentation of Current Medications in the Medical Record	Process	Centers for Medicare & Medicaid Services	419	Yes
CAHPS® <sup>72</sup> Cancer Care Survey – Radiation Therapy Version <sup>73</sup>	Patient Engagement/ Experience	Agency for Healthcare Research and Quality	No <sup>74</sup>	No <sup>75</sup>

In addition to the foregoing measures, it may also be important to consider how to assess areas of quality and practice transformation for which there may not be available measures or areas that may not be appropriate for measurement. For example, currently NQF-endorsed quality measures do not exist for assessing rates of complications from radiation therapy, aspects of end-of-life radiation care, aspects of overuse discussed in *Choosing Wisely*<sup>®</sup>,<sup>76, 77</sup> the timely coordination of concomitant chemotherapy and radiation treatments when clinically recommended, and other potentially important factors of radiation treatment. More structural best practices in radiation therapy, which do not have a corresponding quality measure and may not be appropriate for measurement, include presenting patients at a multi-disciplinary tumor board,<sup>78</sup> presenting patients at “chart rounds” for peer-review,<sup>79</sup> and providing an “end-of-treatment” note to the patient and referring provider. In addition to developing and testing new

<sup>72</sup> CAHPS® is a registered trademark of the Agency for Healthcare Research and Quality (AHRQ).

<sup>73</sup> The CAHPS Cancer Care Survey Version: Radiation Therapy is available here: <https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html>.

<sup>74</sup> Please note that the CG CAHPS® version of the CAHPS® survey has NQF endorsement – NQF numbers 0006 & 0005. Although this specific version builds on the framework of the CG CAHPS® survey, it does not have NQF endorsement.

<sup>75</sup> Please note that the CG CAHPS® version of the CAHPS® survey is included in MIPS. Although this specific version builds on the framework of the CG CAHPS® survey, it is not included in MIPS.

<sup>76</sup> ASTRO *Choosing Wisely* An Initiative of the ABIM Foundation; Ten Things Physicians and Patients Should Question. Sept. 23, 2013 (1-5) and Sept. 15, 2014 (6-10), #10 updated June 21, 2016. <http://www.choosingwisely.org/societies/american-society-for-radiation-oncology/>.

<sup>77</sup> *Choosing Wisely*<sup>®</sup> is a registered trademark of ASTRO.

<sup>78</sup> Many hospitals and freestanding providers use a multidisciplinary meeting to discuss all patients undergoing cancer treatment. These meetings generally include representatives from radiation oncology, medical oncology, surgery, diagnostic radiology, and pathology. Consensus treatment approaches are often result from these discussions.

<sup>79</sup> Most radiation oncology practices discuss each new patient starting treatment. The patient’s clinical presentation is discussed in this peer-review forum, as well technical considerations regarding the radiotherapy treatment plan.

measures,<sup>80</sup> and new measures focused on outcomes in particular, there are several strategies that CMS Innovation Center models can use to engage practices in these types of issues and in clinical quality improvement more broadly. These include:

- **Feedback reports:** Many models provide periodic feedback reports to model participants regarding their clinical and cost performance. A similar strategy could be employed for a potential model on radiation therapy.
- **Peer learning networks:** Many models, including the Oncology Care Model, Bundled Payments for Care Improvement, Comprehensive Primary Care Plus, and Comprehensive Care for Joint Replacement, organize participants into groups so they can identify common problems, share best practice solutions, and work together on quality improvement goals.
- **Practice requirements:** CMS Innovation Center models often identify long-term practice transformation standards that model participants work toward throughout the performance period of the model. In the Oncology Care Model, for example, OCM practices must implement six practice redesign activities, specifically, providing 24/7 access to a clinician with real-time access to the patient’s medical record, using certified EHR technology, using data for continuous quality improvement, providing core functions of patient navigation to OCM beneficiaries, treating patients with therapies consistent with nationally recognized guidelines, and documenting a care plan for each OCM beneficiary that includes the 13 components in the Institute of Medicine Care Management Plan.<sup>81</sup>
- **Monitoring:** CMS can monitor trends in care by analyzing claims data in near real-time, conducting site visits, and other strategies. Section 7.2.7 presents additional discussion about monitoring.

### **7.1.7 Element 7 – Ease of Participant Implementation**

A key consideration for any alternative payment model is operational feasibility, i.e., how easy it would be for participants to build systems, processes, and infrastructure necessary to operationalize their participation in an APM. Participants in a potential radiation oncology model may include physicians and physician group practices. For these physicians, the model design should consider whether participants currently have the data and information they would need, whether the model will fit with participants’ workflow, and whether participants have the operational processes needed. The CMS Innovation Center may also provide participants with data, such as feedback reports, to support practice transformation.

## **7.2 Specific Considerations for Episode Models**

Section 3(b) of the PAMPA requires the Secretary to “submit to Congress a report on the development of an episodic alternative payment model.” In addition to the high-level key design elements discussed in the last section, there are several additional specific factors that the CMS Innovation Center would consider when developing an episodic alternative payment model. These factors each address key questions regarding the design of a potential episode payment model. They include, but are not limited to:

- Potential participants – which providers and suppliers could participate in the model?

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<sup>80</sup> CMS Innovation Center models provide the opportunity to develop and test new measures. CMS has documented a Measure Lifecycle for the development of new measures which can be found at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf>.

<sup>81</sup> <https://innovation.cms.gov/initiatives/Oncology-Care/>.

- Included services – what health care services are included or excluded from the episode-based payment?
- Episode length – how long does the episode last?
- Episode trigger – what starts the episode?
- Setting the payment amount – how are the payment amounts established?
- Determining the payment mechanism – how are payments made to participating providers and suppliers?
- Monitoring – how are beneficiaries and the Medicare program protected?
- Evaluation – what are the effects on quality and spending from the model?

### **7.2.1 Potential Participants**

When designing a model, the CMS Innovation Center determines the types of health care providers (hospitals, physician group practices, physicians, non-physician clinicians, etc.) that can participate.

Radiation services are predominately furnished in two health care settings: freestanding radiation therapy centers and outpatient hospital departments. CMS’s analysis of Medicare claims demonstrates that roughly 38% of radiation treatment delivery services are furnished in freestanding radiation therapy centers and 62% are furnished in hospital outpatient departments. A small amount of radiation services is also furnished in the inpatient hospital setting, at critical access hospitals,<sup>82</sup> and at ambulatory surgical centers.<sup>83</sup>

In the freestanding and outpatient hospital settings, the members of the radiation services care team typically include physicians (radiation oncologists), non-physician practitioners (nurse practitioners, nurses) and specific technical experts (medical physicists and dosimetrists). In certain cases, such as when furnishing certain forms of brachytherapy and stereotactic radiosurgery, other types of physicians (e.g., urologists, obstetricians, neurologists and general surgeons) may be involved in the patient’s care.

Radiation oncologists may practice specifically in a single freestanding radiation therapy center or hospital. Many radiation oncologists, however, practice in multiple settings; that is, they will treat some patients in freestanding centers and others at hospital outpatient departments. Any episode payment model must balance these current practice arrangements as the potential participants are defined.

### **7.2.2 Included Services**

The services included in an episode payment model define the scope of care for which model participants are responsible. Services included in the model would also be generally designed to match the clinical role that model participants will have in the patient’s care. For example, in the Oncology Care Model participants are responsible for the total cost of care over a 6-month episode that begins with chemotherapy treatment for a cancer diagnosis. The design of this model encourages participating practices to improve care coordination, appropriateness of care, and access to care for beneficiaries receiving chemotherapy.

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<sup>82</sup> Based on preliminary assessments of Medicare data, Critical Access Hospitals (CAHs) provide minimal radiation services as compared to standard outpatient hospital departments and freestanding radiation therapy centers.

<sup>83</sup> Ambulatory surgical centers can be paid for the radioactive materials used in brachytherapy procedures and the surgical services required to implant the radioactive materials.



Some radiation oncologists may be the primary source of care for their patients. In other instances, patients see their radiation oncologist for a defined treatment period: the patients may see the radiation oncologist for a relatively short period and then referred to the medical oncologist or another clinician for ongoing care.

### **7.2.3 Episode Length**

In an episode-based payment model, the length of the episode typically dictates the period in which model participants are responsible for the services included in the model. Episodes start with a “trigger event” and last for a defined period. Episode lengths are also generally designed to mimic the length of the clinical intervention and capture related complications.

Episode lengths vary in the CMS Innovation Center’s models. The Oncology Care Model has an episode length of 6 months, which begins when a beneficiary is furnished chemotherapy (although new 6-month episodes can be triggered as long as the patient continues to receive chemotherapy).

To better understand the standard length of a course of radiation, CMS analyzed Medicare claims for beneficiaries who received radiation treatment between January 1, 2014 and December 30, 2015 (a smaller claims window than was used for other analyses included in this Report). These preliminary analyses showed that average Medicare spending for radiation treatment<sup>84</sup> tends to drop significantly after 9–11 weeks after the initial radiation treatment service for most diagnoses, including prostate, breast, lung, and head and neck cancers. Furthermore, based on analysis of Medicare claims for the same beneficiaries, roughly 99% of beneficiaries receiving radiation therapy completed<sup>85</sup> their course of radiation within 90 days of when their radiation treatment was planned.<sup>86</sup> These initial analyses were completed before many of the other analyses presented in this Report, and helped shape the definition of the 90-day “episode” described in section 4.2.

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<sup>84</sup> Radiation treatment was defined by a series of radiation treatment delivery codes used for external beam radiation therapy, brachytherapy and radiopharmaceuticals.

<sup>85</sup> CMS defined “completed” as the last radiation treatment delivery code that is not followed by another radiation treatment delivery code for at least 28 days. This would imply a gap in treatment of over one month.

<sup>86</sup> “Treatment planning” was defined using a series of HCPCS codes that describe radiation therapy planning services. These codes include, but are not limited to, the 77261-77263 radiation therapy planning codes.

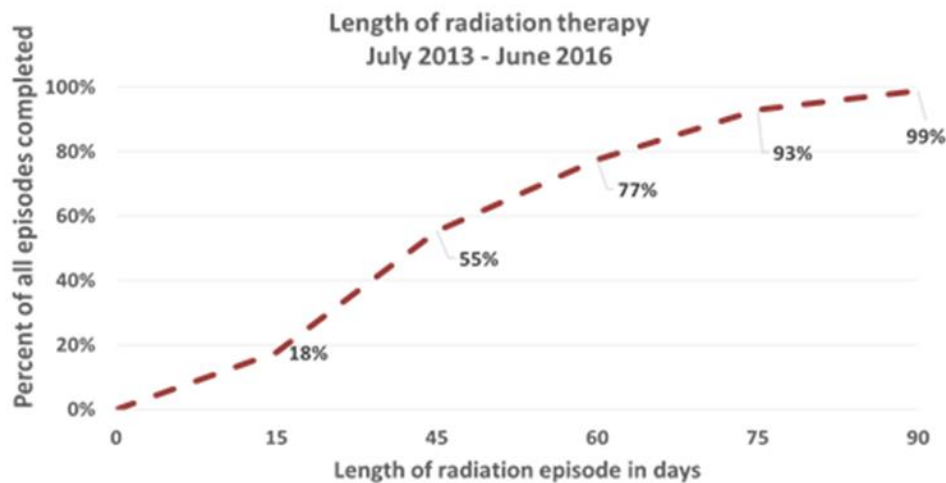


Figure 5: Length of All Radiation Episodes: January 1, 2014 – December 30, 2015

## 7.2.4 Episode Trigger

Episode payment models generally identify an event (or events) that would “trigger” the start of an episode of care. Typically, these events are identified using a code or set of codes that appear in Medicare claims data. For example, episodes are triggered in the Oncology Care Model when a participating practice furnishes certain types of chemotherapy treatments with an accompanying cancer diagnosis.<sup>87</sup>

In radiation oncology, there are multiple services that may be appropriate to use as a trigger for an episode payment model. In selecting a potential episode trigger, one would need to balance when the service happens and how often the service(s) occur as part of a “standard” course of treatment as follows:

- **Initial Consultation:** In a typical course of radiation, most patients begin with an initial consultation with the radiation oncologist; however, many radiation oncology patients may not move on from the initial consultation to treatment. For example, some patients may seek a second opinion or may determine—in conjunction with their physician or independently—that radiotherapy should be deferred.
- **Treatment Planning:** Treatment planning services typically follow the initial consultation. These services include the radiation oncologist determining the type and amount of radiation that a patient receives, the anatomic locations that need to be irradiated, number and size of treatment ports, and the selection of appropriate treatment immobilization devices. Generally, these planning activities precede any radiation treatment. In our analysis, almost all (roughly 95%) Medicare beneficiaries who received radiation therapy also received a planning service near the beginning of their course of treatment.<sup>88</sup>
- **Technical Preparation:** To prepare for treatment, radiation oncologists also provide certain technical preparation and special services, which include modality-specific dose planning, medical radiation physics, and dosimetry, among others. These services are usually furnished prior to the start of radiation treatment.

<sup>87</sup> Qualifying types of chemotherapy include those paid for under Part B and certain types of chemotherapy covered under Part D, such as tamoxifen.

<sup>88</sup> There are other services/codes which could be considered “treatment planning” but are not considered here for purposes of triggering the episode.

## 7.2.5 Setting the Payment Amount

In an episode payment model, the CMS Innovation Center must set the episode price. In most episode payment models, including the Comprehensive Care for Joint Replacement, Bundled Payments for Care Improvement, and the Oncology Care Model, CMS has used historical Medicare payments to establish a baseline. Once the included services, episode length, and triggers are set, CMS can review historical claims and determine actual Medicare spending for the services included in the episode. This historical spending may then serve as a baseline, which may be updated. CMS commonly uses more than one year of historical data in setting this baseline to create greater payment stability. From these data, by adding up all the relevant FFS expenditures, CMS can create individual practice, regional, and national baselines. In some models, particularly those in which participants manage total cost of care across settings, the CMS Innovation Center may also pay participants a monthly care management fee. The payment rate for this fee may be set based on expected costs of implementing the required practice changes and/or furnishing enhanced services. Beneficiary cost sharing (e.g., out-of-pocket costs) may also be taken into consideration when developing episode payment models.<sup>89</sup>

This required Report to Congress was specific to “non-facility” (e.g., freestanding) radiation centers; however, a radiation therapy episode payment model could also apply to hospital outpatient departments where a large percentage of radiation treatment is furnished. The payment could also be constructed to be site neutral, i.e., the same whether the care is furnished in a freestanding radiation center or a hospital outpatient department.

The payment may also be constructed by taking into account extreme outliers—both high- and low-cost cases, limiting the impact of these very high and low-cost cases on payment. CMS Innovation Center models may also apply a defined percentage, referred to as a “discount,” in calculating payment under the model, thus achieving Medicare savings. The OCM discounts currently range from 2.75% to 4% and from 1.5% to 3% in the Comprehensive Care for Joint Replacement model.

A radiation therapy episode payment model would need to consider whether and how to account for differences in costs due to cancer type—such as the differences in costs to treat breast versus lung cancer. A potential payment model would also need to consider how to account for differences in costs due to geographic location. CMS Innovation Center models have used existing geographic indices from CMS payment systems, e.g., the CMS Geographic Practice Cost Index (GPCI),<sup>90</sup> which is used to adjust Medicare PFS payments, and the CMS Hospital Wage Index (HWI),<sup>91</sup> which is used to adjust payments under the Inpatient and Outpatient Hospital Prospective Payment Systems.

When designing a payment model, the CMS Innovation Center considers whether to use practice-specific historical experience only, regional or national experience only, or a blend, and risk adjustment. The CMS Innovation Center has diverse models, with some establishing payments and targets based on practice- (or hospital)-specific experience, while others use only regional or national experience, or a blend. All

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<sup>89</sup> If a potential model uses a treatment modality-agnostic episodic price, this would minimize variation in beneficiary cost sharing (out-of-pocket costs).

<sup>90</sup> Under mandates in Section 1848(e) of the Social Security Act, the Centers for Medicare & Medicaid Services must apply geographic cost indices in the calculation of component RVU input prices.

<sup>91</sup> Section 1886(d)(3)(E) of the Social Security Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts “for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

voluntary models currently have some blend because practices and hospitals that are already lower cost are more likely to join a model with payment targeted to a national average, while higher cost providers would lose money under such a model and are thus unlikely to participate.<sup>92</sup> Payments may also be risk adjusted based on other factors, such as the underlying characteristics of impacted beneficiaries that drive significant resource use (or underuse) that are not adequately reflected in the “baseline” spending used to calculate model payments. The extent of risk adjustment across models depends on the extent to which episode expenditures vary by beneficiary characteristics as captured in claims data.

The CMS Innovation Center must also update the baseline spending amount over time. Models may use a “trend factor” to update the baseline spending to performance period dollars. This trend factor reflects underlying trends in episode expenditures between the baseline and performance periods. The CMS Innovation Center has some models where the trend factor is based on expenditure changes at all non-participants (e.g., OCM) and others where the trend factor includes all episodes, i.e., both participants and non-participants (e.g., BPCI). It is also possible to re-base the payment, i.e., reset the baseline after a certain point in time.

To qualify as an Advanced APM, the payment would need to be based on participants’ performance on MIPS-comparable quality measures. In tying payment to performance on quality indicators, the model could incentivize higher value, lower-cost care.

## **7.2.6 Determining the Payment Mechanism**

Today, Medicare uses a series of payment systems to pay for the health care furnished to beneficiaries. These payment systems are designed around a specific health care provider type—for example, there are specific payment systems for hospitals, physicians, outpatient hospital departments, ambulatory surgical centers, home health agencies, and skilled nursing facilities, among others. As noted in section 4.5.1, the PFS is the payment system applicable to free-standing radiation centers. Many of these systems have unique rules and requirements.

The mechanism for paying participants in an episode payment model must be considered in the model design. Within many of the CMS Innovation Center’s models, model participants continue to be paid using Medicare’s existing payment systems. For example, participants in the Oncology Care Model are paid regular Medicare FFS payments in the model. As described in section 5.1, the Oncology Care Model uses a two-part payment approach to create incentives to improve the quality of care and furnish enhanced services for beneficiaries undergoing chemotherapy treatment for a cancer diagnosis. These two forms of payment include a Monthly Enhanced Oncology Services (MEOS) Payment and a Performance-Based Payment for OCM episodes. The Performance-Based Payment for OCM episodes is calculated retrospectively through a semi-annual reconciliation based on the practice’s reductions in Medicare expenditures below a target price, adjusted based on the practice’s achievement on the Oncology Care Model Quality Measures.

Participants under an episode payment model could also be paid prospectively, meaning they would receive the episode-payment in a lump sum at the beginning or completion of the episode. In practice, this payment may be similar to IPPS, which makes a single payment to the hospital for all services furnished during the beneficiary’s stay.

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<sup>92</sup> Bundle Medicare’s Payments to Health Care Providers <https://www.cbo.gov/budget-options/2013/44898>.

## 7.2.7 Monitoring

The CMS Innovation Center uses several monitoring strategies to help protect beneficiaries and the Medicare program. These monitoring activities track model participants and identify potential patient safety, compliance or other concerns, and include:

- **Claims monitoring:** CMS can monitor claims on a near real-time basis to determine if utilization and outcome patterns have changed significantly as compared to historical trends. This type of monitoring is critical when there are concerns regarding access to care, and can track health outcomes such as mortality and increased hospital or physician visits, among other trends. This claims monitoring is currently being done in Medicare programs such as the DME competitive bidding program.
- **Site-visits:** The CMS Innovation Center model teams or CMS contractors acting on their behalf go on site to evaluate a participant's adherence to model standards and requirements, practice transformation goals, and other activities. These visits help the CMS Innovation Center determine whether practices are facing common challenges and building cooperative solutions.
- **Practice and beneficiary surveys:** The CMS Innovation Center conducts surveys of model participants and beneficiaries.

## 7.2.8 Evaluation

Section 1115A(b)(4) of the Act requires the CMS Innovation Center to conduct an evaluation of each CMS Innovation Center model test, and it specifies that each evaluation must include an analysis of the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria, as well as changes in program spending by reason of the model. As noted above, the Secretary of Health and Human Services shall take this evaluation into account in decisions to expand the duration and scope of a model under 1115A(c) of the Act.

The CMS Innovation Center, using independent evaluators, routinely and rigorously evaluates the impact of each model on quality and cost. The evaluations include advanced statistical methods and carefully defines and selects comparison groups<sup>93</sup>, as appropriate, to ensure that models deemed to be successful represent high-value investments of taxpayer dollars. Central to this evaluation approach is the recognition that evaluators must not only assess results, but also understand the context that generates those results.

For each model, the CMS Innovation Center tailors the collection of qualitative information to the needs of the model with the goal of integrating the qualitative information with quantitative findings in order to best identify and understand the impact of the model.

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<sup>93</sup> Under a potential model, comparisons groups could be matched as closely as possible to participating practices based on a variety of attributes, including size of the practice, setting (hospital-based or freestanding), services offered, ownership, location, insurance mix, and patient mix.

## 8. Stakeholder Consultation

### 8.1 CMS Public Forum Listening Session

On May 3, 2017, CMS held a public forum listening session so stakeholders could provide input on design options for an alternative payment model for radiation therapy services to be included in this report to Congress. At the meeting, CMS also presented background information on the report and aggregate claims data on the utilization of radiation therapy services in the Medicare FFS population.

Over 140 stakeholders attended the listening session. Attendees participated in-person at CMS headquarters and virtually through a WebEx display and phone. CMS accepted public comment in person and over the phone. CMS also accepted written comments by email until May 22, 2017. Stakeholders raised many key issues at the public forum, including:

- **Rural Providers:** Several commenters expressed concern about how current payments in the Medicare PFS and the OPFS lead to underpayments for certain rural areas. Speakers specifically discussed how Medicare PFS Geographic Practice Cost Indices calculations may not accurately reflect certain practice expenses (such as purchasing a linear accelerator) that are consistently high across rural and urban areas. They also discussed that they have fewer suppliers (which reduces price competition, and availability of product support) and must incentivize specialized, highly technical medical staff (medical physicists, dosimetrists, etc.) to stay. Commenters were concerned that these geographic adjustments would be incorporated into a potential bundle and could negatively impact rural areas. Another commenter requested that CMS refine the “direct supervision” requirements for “incident to” radiation oncology services in outpatient hospital settings to include “virtual supervision” through telemedicine, which they said could expand access in rural areas. One commenter noted that rural challenges remain and are larger than a discussion about a potential model for radiation therapy. Commenters also suggested various ways to better accommodate rural areas in a potential model, such as limiting a potential discount on episode-based payments to rural participants.
- **Site Neutrality:** Commenters were concerned that CMS would focus a potential radiation therapy model only on payments for freestanding radiation therapy centers and exclude hospitals. Several commenters noted how radiation oncologists tend to have varying arrangements with freestanding clinics and hospitals, and that a significant portion of radiation care is furnished in the hospital setting. Other commenters noted that if settings are excluded from a potential model, it would encourage the shifting of certain patients from one setting to another, which could negatively impact care and raise costs. Commenters stressed the importance of site neutrality in payments and said hospital outpatient departments and the physicians who practice there should be included.
- **Overlap with the Oncology Care Model:** Several commenters were concerned about the overlap of a potential radiation oncology model with OCM. Commenters noted that many patients who “trigger episodes” due to their use of chemotherapy under the OCM also receive radiation. One commenter who currently participates in OCM specifically expressed concern about being allowed to participate in both models. Of note, many oncology practices are large integrated practices that are staffed by medical oncologists, radiation oncologists, surgeons, and other specialists. Commenters expressed interest in a long-term strategy of developing a model that is agnostic to treatment and more disease-specific (e.g., a breast cancer model).
- **Quality Measurement and Improvement:** Commenters stated that any radiation therapy model should include evidence-based quality measures that can be used to improve patient care. Commenters suggested specific measures, including:

- Rates of complications from radiation therapy through claims data using specific ICD-10 diagnosis codes;
- Certain patient-satisfaction metrics;
- Adherence to clinical guidelines, such as guidelines developed by specialty societies (such as ASTRO and ACRO) and from the Choosing Wisely® campaign; and
- Measures that are comparable to those measures used under MIPS.

Commenters also said CMS should work to ensure that model participants are not overly burdened by having to report too many measures. Other commenters said that if CMS were to develop a model, the agency should make modest payments for quality and care coordination activities. Other commenters noted that the specialty societies such as ASTRO, ACR and ACRO have developed accreditation programs that provide a basic assessment of a radiation therapy clinics' capabilities and could be incorporated into a model to support high quality care, although there are provider concerns about the costs associated with mandatory accreditation.

- **Pricing Stability:** Stakeholders described the challenge for physicians and radiation therapy clinics in dealing with year-over-year changes in Medicare payments under the PFS (discussed in section 4.6.1). Stakeholders emphasized the need for pricing stability in a potential radiation therapy model, and noted that any future pricing arrangement should be “delinked” from the PFS.
- **Specific Proposals:** Commenters also offered specific designs for an episode alternative payment model for radiation therapy. These designs included:
  - At the in-person meeting (and also through more detailed written comments), a stakeholder discussed a potential episode payment model that would establish payments for all of the radiation services furnished during a 90-day course of treatment. The model would include five primary disease sites<sup>94</sup> and two secondary disease sites.<sup>95</sup> Participants in the model would receive a portion of the episode payment at the beginning and the remainder when the episode concluded. The proposed model would also include a monthly Patient Engagement and Care Coordination Fee of \$160 per month to support care coordination, improved access and other activities. The CMS Innovation Center also received letters of support for this potential payment model from other stakeholders, including letters from many radiation oncologists.
  - Another stakeholder submitted information regarding its ongoing alternative payment model with a commercial payer. Under that model, prospective payments are made for all radiation services furnished within a 90-day course of radiation. The model includes all patients with 14 types of cancer, and payments encompass all radiation therapy modalities, except radiopharmaceuticals. Based on its experience with this model, the stakeholder recommended that any future model should include as many diagnoses as possible, should last for at least 5 years, and should emphasize stability in pricing, among other factors. Another stakeholder recommended use of this commercial model in Medicare.

## **8.2 Stakeholder Responses to other CMS Initiatives**

In addition to the public forum listening session described in section 8.1, there had been several earlier opportunities for radiation oncology stakeholders to provide comments to CMS on issues related to the

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<sup>94</sup> Prostate, Breast, Lung, Head and Neck and Lower Gastrointestinal Cancers. In their detailed comments to CMS, the specialty society also provided the specific ICD9 and 10 codes that would make up these types of cancer.

<sup>95</sup> Brain and Bone metastases.

development of APMs. These opportunities included Notices of Proposed Rulemaking, Requests for Information, and Requests for Comment published by CMS.

The commenters included trade and professional associations, provider groups, and manufacturers, among others. Themes that emerged across all comment opportunities include stakeholders' general support of expanding the availability of Advanced APMs focused on radiation oncology under the MACRA's Quality Payment Program. The CMS Innovation Center reviewed these responses while developing this report to Congress.

### **8.3 Letters of Intent for Physician-Focused Payment Models**

On November 4, 2016, CMS published the Calendar Year 2017 Final Rule on the Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models (PFPM).<sup>96</sup> This Final Rule established the Secretary's ten criteria for use by the PTAC in the evaluation of PFPMs.

The Physician-Focused Payment Model Technical Advisory Committee (PTAC), created by Section 101(e)(1) of MACRA, was convened to review proposed PFPMs and provide comments and recommendations to the Secretary of Health and Human Services regarding whether such models meet the Secretary's PFPM criteria.<sup>97</sup> The PTAC can recommend limited-scale testing, implementation, implementation with a high priority, or not recommend proposed PFPMs.

To date, the PTAC has received two letters of intent for radiation oncology-focused PFPMs.

In October and November 2016, respectively, the American Society for Radiation Oncology and the American College of Radiation Oncology each submitted a Letter of Intent (LOI) providing general overviews of their forthcoming proposals for Advanced APMs for radiation oncology services.

Both suggested Advanced APMs that include the cancer diagnoses that are typically treated with radiation therapy. Each proposed an episodic case rate payment model with target pricing with one that ended 90 days after the last radiation therapy treatment, while the other's duration was a total of 90 days. The CMS Innovation Center reviewed the content of these LOIs while developing this report to Congress.

## **9. Summary**

This Report to Congress describes the provision of radiation therapy services, why Medicare beneficiaries may need radiation therapy services, and how Medicare pays for these services.

This Report also articulates several alternative payment model design considerations, including the type of alternative payment model; how the model is expected to result in clinical practice transformation; the rationale for such a model; the potential scale; its alignment with other initiatives; how the model may measure improved clinical quality and patient experience; and, how readily providers may participate.

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<sup>96</sup> 42 C.F.R. § 414, 495. Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models. Final Rule. November 4, 2016.

<sup>97</sup> A PFPM is an APM that includes Medicare as a payer; physicians or other eligible clinicians play a core role in implementing the payment methodology; and targets quality and costs of services physicians or other eligible clinicians provide, order, or significantly influence.



An analysis of these model dimensions suggests that a potential episode payment model on radiation therapy could have several positive benefits. Such a model could:

- Maintain or enhance clinical quality and patient experience for those cancer patients who receive radiation by emphasizing high-value therapies and encouraging effective specialty care;
- Encourage peer-to-peer learning, spread clinical best practices, and accelerate future practice change; and,
- Maintain or reduce Medicare program expenditures.

An episode payment model could also address many of the challenges with the current payment systems. Under a potential model, the CMS Innovation Center could streamline payment for radiation therapy, and identify and test alternative rate setting strategies for services that involve expensive capital equipment, and generate more year-to-year stability in radiation payments.

This Report presents a series of important considerations that are critical to effective model design. CMS would need to consider these issues before moving forward with any future episode payment model on radiation therapy services. In addition, CMS would also continue to seek input from stakeholders on these important issues.

## **Appendix A. Patient Access and Medicare Protection Act (PL 114-115), Section 3**

### **SEC. 3. TRANSITIONAL PAYMENT RULES FOR CERTAIN RADIATION THERAPY SERVICES UNDER THE MEDICARE PHYSICIAN FEE SCHEDULE.**

(a) **IN GENERAL.**—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended—

(1) in subsection (b), by adding at the end the following new paragraph:

“(11) **SPECIAL RULE FOR CERTAIN RADIATION THERAPY SERVICES.**—The code definitions, the work relative value units under subsection (c)(2)(C)(i), and the direct inputs for the practice expense relative value units under subsection (c)(2)(C)(ii) for radiation treatment delivery and related imaging services (identified in 2016 by HCPCS G-codes G6001 through G6015) for the fee schedule established under this subsection for services furnished in 2017 and 2018 shall be the same as such definitions, units, and inputs for such services for the fee schedule established for services furnished in 2016.”; and

(2) in subsection (c)(2)(K), by adding at the end the following new clause:

“(iv) **TREATMENT OF CERTAIN RADIATION THERAPY SERVICES.**—Radiation treatment delivery and related imaging services identified under subsection (b)(11) shall not be considered as potentially misvalued services for purposes of this subparagraph and subparagraph (O) for 2017 and 2018.”

(b) **REPORT TO CONGRESS ON ALTERNATIVE PAYMENT MODEL.**— Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the development of an episodic alternative payment model for payment under the Medicare program under title XVIII of the Social Security Act for radiation therapy services furnished in nonfacility settings.