Illinois Health and Hospital Association

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ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M

SUBJECT: **CMS Proposed Specialty Care Models: the Radiation Oncology Model and the End-Stage Renal Disease Treatment Choices Model**

On July 18, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register (FR)* two proposed specialty care models specific to radiation oncology and end-stage renal disease (ESRD) (*Federal Register*, Vol. 84, No. 138, pages 34478-34595). The provisions of this proposed rule are scheduled to take effect beginning January 2020 and would be mandatory if a facility is chosen to participate. Comments on this proposed rule are due to CMS no later than Sept. 16.

Executive Summary

CMS is proposing these two models under authority granted to the CMS Innovation Center by Section 1115A of the Social Security Act. Under this authority, CMS can test innovative payment and service delivery models expected to reduce Medicare, Medicaid and Children's Health Insurance Program (CHIP) expenditures, while preserving or enhancing the quality of care furnished to these programs' beneficiaries. The two models outlined in this proposed rule are specific to Medicare fee-for-service (FFS) beneficiaries.

CMS' first proposed model is the Radiation Oncology (RO) model. The RO model is meant to test whether prospective, episode-based payments for radiotherapy (RT) services would reduce Medicare program expenditures, while preserving or enhancing the quality of care for certain types of cancer. Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode. CMS proposes to implement the RO model over five years beginning in 2020 and ending Dec. 31, 2024, with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024.

CMS' second proposed model is the ESRD Treatment Choice (ETC) model. The ETC model is meant to test whether CMS can incentivize ESRD facilities and clinicians managing adult Medicare FFS beneficiaries with ESRD to work with their patients to achieve increased rates of home dialysis utilization and kidney and kidney-pancreas transplantation. Both healthcare providers and patients indicate that home dialysis and kidney transplantation are preferable alternatives to in-center hemodialysis, but the utilization rates of these services in the U.S. remain below rates in other developed nations. CMS proposes several upward and downward payment adjustments based on home dialysis utilization and transplantation rates between Jan. 1, 2020 and June 30, 2026.

If a facility or clinician is selected to participate in one of these programs, participation is mandatory. More details on both proposed models are provided below.

Proposed Radiation Oncology Model (RO)

Scope of Model: CMS proposes testing the RO model for five years, beginning Jan. 1, 2020 through Dec. 31, 2024. CMS is considering delaying implementation until April 1, 2020, and is soliciting feedback on whether such a delay would be helpful or necessary. An April 1, 2020 start date would only affect the length of the first year of the model, which would then be nine months long. All other model years would be 12 months long.

RO Model Participation: The RO model will impact Medicare-participating hospital outpatient departments (HOPDs), physician group practices (PGPs), and freestanding radiation therapy centers that furnish RT services. CMS will randomly select a nationally representative sample of core-based statistical areas (CBSAs) for RO model implementation, and all of the HOPDs, PGPs, and freestanding radiation therapy centers in sampled CBSAs will be **required** to participate. Each entity will be assigned as either:

- Professional Participants: a Medicare-enrolled PGP identified by a single taxpayer identification number (TIN) that furnishes only the professional component of RT services at either a freestanding RT center or an HOPD;
- Technical Participants: a Medicare-enrolled HOPD or freestanding RT center, identified by a single CMS certification number (CCN) or TIN, which furnishes only the technical component of RT services; or
- Dual Participants: a Medicare-enrolled entity that furnishes both the professional and technical components of an episode for RT services through a freestanding RT center, identified by a single TIN.

Hereinafter, professional, technical and dual participants will simply be referred to as RO participants.

CMS plans to sample 40% of all eligible RO episodes in CBSAs nationwide. CBSAs and their zip codes selected for participation will be published on the RO website once the final rule is displayed.

Certain entities will be excluded from the RO model, including any PGPs, freestanding radiation therapy centers and HOPDs that are:

- Classified as an ambulatory surgery center (ASC), critical access hospital (CAH) or prospective payment system-exempt cancer hospital;
- Furnish RT services only in Maryland, Vermont, or the U.S. Territories; or
- Participates in or is identified as eligible to participate in the Pennsylvania rural health model.

If an RO participant undergoes changes such that one or more of the proposed exclusion criteria becomes applicable during the performance period, then that RO participant would be excluded moving forward. Conversely, if a PGP, freestanding radiation therapy center, or HOPD satisfies the exclusion criteria when the RO model begins and subsequently experiences a change such that the proposed exclusion criteria no longer apply, and the PGP, freestanding radiation therapy center, or HOPD is located in one of the randomly selected CBSAs, then participation would be required moving forward.

Beneficiary Population: Beneficiaries are included in the RO model if (1) Medicare is the individual's primary payer when an RT episode begins, (2) the individual is a traditional FFS Medicare enrollee; (3) the individual receives RT services from an RO participant, and (4) the individual has one of the 17 included cancer diagnoses (see below). Beneficiaries would be responsible for the typical coinsurance amount (20%). Individuals enrolled in any Medicare managed care organization (e.g. Medicare Advantage); enrolled in a PACE (Programs of All-Inclusive Care for the Elderly) plan; not in a Medicare hospice benefit period; or covered under United Mine Workers are not included.

If an RO beneficiary stops meeting any of the proposed criteria or triggers any of the exclusion criteria before radiation treatment begin (see "technical component" below), then the episode would be considered incomplete and payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process (see payment information below). Additionally, if traditional Medicare stops being an RO beneficiary's primary payer after the TC of the episode has begun, then regardless of whether the beneficiary's course of RT treatment was completed, the episode will be considered incomplete and the RO participants will receive only the first installment of the episode payments. Finally, if the beneficiary dies or enters hospice during an episode, the RO participants would receive both installments of the episode payment, regardless of whether the RO beneficiary's course of RT has ended.

Included Cancer Types: CMS included a cancer type in the RO model if it is commonly treated with radiation and has demonstrated pricing stability. The included cancer types are: anal cancer; bladder cancer; bone metastases; brain metastases; breast cancer; cervical cancer; central nervous system (CNS) tumors; colorectal cancer; head and neck cancer; kidney cancer; liver cancer; lung cancer; lymphoma; pancreatic cancer; prostate cancer; upper gastrointestinal (GI) cancer; and uterine cancer. See Table 1 on *FR* page 34498 for more information.

Episode Length and Trigger: Episodes will last 90 days. Episodes start on the date of service that a professional or dual participant furnishes the initial treatment planning service, so long as a technical or dual participant furnishes an RT service within 28 days of the treatment planning service (see Table 2 on *FR* pages 34501-34502 for a list of RT service HCPCS codes). If an RT service is not furnished within 28 days, then no episode will have occurred and any payment made will be recalled via CMS's incomplete episode policy.

Included Modalities: CMS proposes to include the following modalities in the RO model because they are the most commonly used to treat the 17 included cancer types: various types of external beam RT, including 3D conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy.

Pricing Methodology: Each episode of RT will have two components: professional and technical:

- Professional Component (PC): RT services that may only be furnished by a physician.
- Technical Component (TC): RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and costs related to RT services.

An episode of RT will be furnished either by (1) two separate RO participants (PC and TC) or (2) a dual participant that furnishes both the PC and TC of an episode.

CMS will use an eight-step methodology to determine payments to RO participants:

1. *National base rate*. CMS will start by calculating national base rates for the PC and TC for each cancer types. Each base rate represents the average cost for an episode of care for each of the include cancer types, based on claims from RT episodes that occurred from 2015 through 2017 and are attributed to HOPDs. Unless CMS engages in a broad rebasing, these rates would be fixed for all five years of the RO model. Base rates can be seen in Table 3 on *FR* page 34506.
2. *Trend factor*. CMS will apply trend factors to the base rates for both PC and TC to reflect current trends in payment and volume of RT services.
3. *Case mix and historical adjustments.* CMS will adjust each of the 34 trended national base rates to account for each participant's case mix history and historical experience.
4. *Discount factors*. CMS will then reduce the payment amounts that result from steps 1-3 by a proposed discount factor of 4% for the PC and 5% for the TC.
5. *Withholds*. CMS will further adjust the payment by applying an "incorrect payment withhold" to both the PC and TC portions of the payment, a quality withhold to the PC and a patient experience withhold to the TC. See below for more details on these withholds.
6. *Geographic adjustment*. CMS will apply geographic adjustments to the payment amounts based on where RT services are furnished pursuant to existing geographic adjustment processes in the outpatient prospective payment system (OPPS) and physician fee schedule (PFS).
7. *Coinsurance*. CMS will apply beneficiary cost sharing to the PC and TC payment amounts.
8. *Sequestration*. CMS will apply a 2% sequestration adjustment to the remaining payment amount.

Examples of this methodology can be found in Tables 5 and 6 on *FR* pages 34511 and 34512. CMS will make payments to RO participants in two equal installments, one at the start of an episode and one upon completion. At the end of each performance year, CMS will reconcile the withhold amounts described below. RO participants will be at 100% risk for any costs they incur above the reconciled payment amounts they receive.

Payment Withholds and Reconciliation: CMS has proposed three withhold amounts within the pricing methodology outlined above. An incorrect payment withhold will be applied to both the PC and TC portions of the payment. Additionally, the PC portion will be subject to a quality withhold and the TC will be subject to a patient experience withhold.

- Incorrect Payment Withhold: CMS will withhold 2% of both the PC and TC payments to minimize the amount of money CMS may need to recoup due to the provision of duplicate RT services or incomplete episodes. A duplicate RT service might occur should more than one unique entity bill for either professional or technical RT services within a single episode, such as if a beneficiary changes providers in the middle of an episode. An episode is considered incomplete under various scenarios, including: (1) when an RT treatment is not furnished within 28 days following an RT treatment planning services; (2) traditional Medicare stops being the primary payer for a beneficiary; or (3) an beneficiary stops meeting the criteria for inclusion in the model. CMS will determine through the reconciliation process whether an RO participant is eligible to receive all or some of the withhold payment back, or whether the participant owes CMS additional funds to repay incorrect payments. CMS outlines specific rules regarding the reimbursement for incomplete episodes that are dependent on the reason the episode is considered incomplete. See *FR* pages 34512-34514 for more information.
- Quality Withholds: CMS will apply a 2% withhold to the PC portion for quality measures (quality measures are described below). Participants may earn back some or all of this withhold based on their aggregate quality score (AQS).
- Patient Experience Withholds: Starting in the third performance year, CMS will also apply a 1% withhold to the TC portion. Participants will be able to earn this withhold back based on performance on patient experience measures informed by the CAHPS Cancer Care Radiation Therapy survey.

Collection of Quality Measures, Clinical Data Elements and CAHPS Survey Results: CMS proposes requiring the collection of four quality measures starting March 2021, including:

- Oncology: Medical and Radiation – Plan of Care for Pain (National Quality Forum (NQF) #0383; CMS Quality ID #144);
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134);
- Advance Care Plan (NQF #0326; CMS Quality ID #047); and
- Treatment Summary Communication – Radiation Oncology (note – this measure is not currently NQF endorsed).

CMS intends to add or remove measures in future performance years using notice and comment rulemaking. CMS will require quality measures to be reported in aggregate, and CMS proposes that these data be reported for all applicable patients, not just Medicare beneficiaries.

CMS will also require the reporting of certain clinical data elements not available in claims or captured in the proposed quality measures for RO beneficiaries with the following cancer types: prostate, breast, lung, bone metastases, and brain metastases. The specific data elements and reporting standards will be defined prior to the start of the RO model and will be communicated on the RO website.

CMS will provide RO participants with the necessary mechanisms to input quality measure and clinical data, including a template, a secure portal for data submission and education and outreach services.

Finally, results from selected patient experience measures based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy will also be required beginning in the third year of the RO model. CMS proposes having a contractor administer the survey beginning April 1, 2020.

Aggregate Quality Score (AQS): The AQS will be used to determine the amount of the quality withhold that an RO participant earns back. Specifically, CMS will calculate the AQS as the sum of the equally weighted scores for quality performance and clinical data. In other words, CMS proposes to weight 50% of the AQS on the successful reporting of required clinical data and the other 50% of the AQS on quality measure reporting. See Tables 8 and 9 for examples of AQS calculation on *FR* page 34521.

Quality Payment Program: CMS intends for the RO model to qualify as an advanced APM and MIPS APM under the quality payment program (QPP). CMS will establish an individual practitioner list under this model. Before the start of each performance year, CMS will ask professional and dual participants to certify the list so that the agency may determine whether practitioners on the list qualify for APM incentive payment or should be scored for MIPS. HOPDs will not be included as they are not subject to the QPP.

Waivers: In order to test RO, CMS proposes the waiver of certain Medicare requirements, including:

- The two percentage point Hospital Outpatient Quality Reporting Program payment reduction for hospitals that fail to meet the reporting requirements under the program for Ambulatory Payment Classifications (APCs) that contain the new RO-specific HCPCS codes. For APCs not included in the model, OPPS payments will still be subject to the payment reduction when the hospital does not meet reporting requirements;
- The application of the MIPS payment adjustment factors to certain RO payments;

- The inclusion of TC payments in calculating the MACRA APM incentive payment amount;
- The Section 603 site-neutral payment policy governing payments for non-excepted off-campus provider based departments participating under the RO model;
- Certain claims appeals requirements; and
- Other general payment waivers.

Proposed End-Stage Renal Disease (ESRD) Treatment Choices Model

Scope of Model: CMS proposes testing the ESRD Treatment Choices Model (ETC) for six years and six months, beginning Jan. 1, 2020 and ending June 30, 2026. CMS is considering delaying implementation until April 1, 2020, and is soliciting feedback on whether such a delay would be helpful or necessary. An April 1, 2020 start date would impact all intervals within the timelines outlined below; all timelines would remain the same length, but start and end dates would be adjusted to occur three months later.

ETC Participation: CMS proposes requiring all managing clinicians and ESRD facilities located in randomly selected hospital referral regions (HRRs) to participate in ETC. HRRs, composed of groups of zip codes, were created by the Dartmouth Atlas Project and are meant to distinguish the referral patterns to tertiary care for Medicare beneficiaries. CMS proposes to randomly select 50% of HRRs across all 50 states and Washington, D.C. U.S. territories will be excluded from the sample. All HRRs that are not selected will be included in the comparison group for the purposes of evaluating ETC.

ETC Beneficiary Population: CMS is defining ESRD beneficiaries as individuals receiving dialysis or other services for ESRD, up to and including the month in which they receive a kidney or kidney-pancreas transplant. ESRD beneficiaries can be attributed to both ESRD facilities and managing clinicians. CMS also proposes attributing pre-emptive transplant beneficiaries, or Medicare beneficiaries who received a kidney or kidney-pancreas transplant prior to beginning dialysis, to managing clinicians for purposes of calculating the transplant rate. ESRD beneficiaries and pre-emptive transplant beneficiaries are mutually exclusive. CMS outlines several beneficiary exclusion on page 34549 of the *FR*.

Payment Adjustments: CMS proposes adjust payments in two ways:

1. Home Dialysis Payment Adjustment (HDPA): CMS proposes to positively adjust payments for home dialysis and home dialysis-related services billed by ETC participants for claim dates during calendar year (CY) 2020 through CY2022. HDPAs will decrease over time: +3% in CY 2020, +2% in CY 2021 and +1% in CY 2022.
2. Performance Payment Adjustment: As HDPAs decrease, CMS will adjust payment either upwards or downwards for dialysis and dialysis-related services based on each ETC participant's home dialysis and transplant rates. Calculation of these rates is described in the next section. The magnitude of the potential positive and negative payment adjustments would increase over time. The payment adjustments proposed for the ETC would start at the same 5% level in 2020 as the MIPS payment adjustment. Additionally,

negative adjustments will be larger than positive adjustments, and CMS proposes that the negative adjustments would be greater for ESRD facilities than for managing clinicians.

a. CMS is proposing low-volume threshold exclusions for the PPA. For ESRD facilities, CMS proposes excluding those facilities that have fewer than 11 attributed beneficiary-years during a given measurement year from the application of the PPA during the corresponding PPA period. For managing clinicians, CMS proposes excluding managing clinicians who fall below the bottom 5% of ETC participants who are managing clinicians in terms of the number of beneficiary years for which they bill during the measurement year.

Performance Measurement: CMS proposes calculating home dialysis and transplant rates for ETC participants for each measurement year.

- Home Dialysis Rate: the rate of ESRD beneficiaries who dialyzed at home during the relevant measurement year.
    - For both ESRD facilities and managing clinicians, the home dialysis rate denominator will be those months during which attributed ESRD beneficiaries received maintenance dialysis either at home or in an ESRD facility. The numerator will be those months during which attributed ESRD beneficiaries received maintenance dialysis at home.
    - For both facilities and managing clinicians, the numerator and denominator will be converted to total beneficiary years, where one beneficiary year is comprised of 12 beneficiary months.
- Transplant Rate: the rate of ESRD beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC participants who receive a kidney or kidney-pancreas transplant during each measurement year. Excluded from this rate are beneficiaries that turn 75 or older at any point during a month in the measurement year, and any months during which an ESRD beneficiary is in a skilled nursing facility.
    - ESRD Facilities: For ESRD facilities, the denominator will be those months during which attributed ESRD beneficiaries received maintenance dialysis at home or in an ESRD facility. The numerator will be total number of attributed beneficiaries who received a kidney or kidney-pancreas transplant during the measurement year.
    - Managing Clinicians: For managing clinicians, the denominator and numerator will include preemptive transplant beneficiaries (i.e., beneficiaries who receive transplants before beginning dialysis) in addition to ESRD beneficiaries. The denominator will be those months during which attributed ESRD beneficiaries received maintenance dialysis at home or in an ESRD facility, plus the total number of attributed months for pre-emptive transplant beneficiaries during the measurement year. The numerator would be the number of attributed ESRD beneficiaries who received a kidney or kidney-pancreas transplant during the

measurement year, plus the number of preemptive transplant beneficiaries attributed to the managing clinician for the measurement year.
    - If a beneficiary who receives a transplant during a measurement year returns to dialysis during the same measurement year, the beneficiary would remain in the numerator to acknowledge the efforts of the managing clinical in facilitating the transplant and to hold the managing clinician harmless for transplant failure which may be outside of their control.
- For both facilities and managing clinicians, the numerator and denominator will be converted to total beneficiary years, where one beneficiary year is comprised of 12 beneficiary months.

Benchmarking and Scoring: CMS proposes two sets of benchmarks to use in calculating scores for ETC participants:

1. The first set of benchmarks is used to calculate an achievement score for ETC participants on both the home dialysis and transplant rates. This benchmark is constructed based on historical rates of home dialysis and transplantation in comparison geographic areas, with the intent to increase the rates achieved by ETC participants above geographic comparison areas in future years.
2. The second benchmark set is used to calculate an improvement score for each ETC participant on both the home dialysis and transplant rates. This benchmark is constructed based on historical rates of home dialysis and transplantation by the specific ETC participant during the initial benchmark year. CMS proposes calculating the improvement score by comparing each ETC participant's performance on home dialysis and transplantation against past individual ETC participant-specific rates. CMS intends for this to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplantation.

Quality Measures: CMS proposes two ESRD facility quality measures for the ETC which are already collected and should present no additional burden to ETC participants:

- Standardized Mortality Ratio (NQF #0369): Risk-adjusted standardized mortality ratio of the number of observed deaths to the number of expected deaths for patients at the ESRD facility; and
- Standardized Hospitalization Ratio (NQF #1463): Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for patients at the ESRD facility.

CMS also proposes that ETC ESRD facility participants would still be included in the ESRD quality incentive program (QIP) and required to comply with QIP requirements, including being subject to a sliding scale payment reduction if an ESRD facility's total performance score does not meet or exceed the minimum total performance score specified by CMS for the payment year.

Further, ETC Participants who are managing clinicians and are MIPS eligible clinicians would still be subject to MIPS requirements and payment adjustment factors, and those in a MIPS APM would be scored using the APM scoring standard. ETC Participants who are managing clinicians and who are in an Advanced APM would still be assessed to determine whether they are Qualifying APM Participants (QPs) who, as such, would earn the APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment.

Overlap with Other Innovation Center Models and CMS Programs: The ETC would overlap with several other CMS programs and models, and CMS will try to account for this overlap as follows:

- ESRD Quality Incentive Program (ESRD QIP): CMS proposes applying the ETC facility HDPA and PPA prior to the application of the ESRD QIP payment adjustment to the ESRD PPS per treatment payment amount;
- Merit-based Incentive Payment System (MIPS): CMS proposes that the managing clinician HDPA and PPA under the ETC model will apply to the amount otherwise paid under Medicare Part B, but will occur prior to the application of the MIPS payment adjustment factors;
- Kidney Care First Model (KCF) and the Comprehensive Kidney Care Contracting (CKCC) Models: The KCF and CKCC are optional Innovation Center models focused on beneficiaries with CKD and ESRD. These models will run from Jan. 1, 2020 through Dec. 31, 2025 with five years of financial accountability overlap with the ETC beginning Jan. 1, 2021. CMS proposes that the types of entities eligible to participate in these models [KCF practices and Kidney Contracting Entities (KCEs)] would be permitted to participate in either the KCF or one of the CKCC models within regions where the ETC Model will be in effect. Payment adjustments under the ETC model will be counted as expenditures for purposes of the KCF and CKCC Models. Both models would include explicit incentives for participants when beneficiaries receive kidney transplants; and a participant in both models will be eligible to receive both types of adjustments under the ETC model (the HDPA and PPA), as well as a Kidney Transplant Bonus under the KCF and CKCC models;
- Comprehensive ESRD Care (CEC) Model: The CEC is a voluntary Innovation Center model for ESRD dialysis facilities, nephrologists and other providers and suppliers that focuses on beneficiaries with ESRD. The CEC Model will end on Dec. 31, 2020, and therefore, will overlap for one year with the proposed ETC. CMS proposes that ETC participants could be selected from regions where there are participants in the CEC Model; and
- All other Medicare APMs: For other Medicare APMs that focus on total cost of care, CMS proposes any increase or decrease in program expenditures that are due to the ETC would be counted as program expenditures to ensure that the Medicare APM continues to measure the total cost of care to the Medicare program.

Medicare Program Waivers: In order to test ETC, CMS proposes waiving certain Medicare requirements, including:

- ESRD PPS and PFS payment system requirements to the extent necessary to make the payment adjustments proposed for ETC participants;
- Requirements that payments otherwise made to a provider of services or a renal dialysis facility under the system for renal dialysis services be reduced by up to 2%, if the provider of services or the renal dialysis facility does not meet the requirements of the ESRD QIP for a payment year;
- Payment adjustments made under ETC would not change beneficiary cost sharing from the regular Medicare program cost sharing for the related Part B services that were paid for beneficiaries who receive services from ETC participants; and
- Several requirements for the provision of kidney disease education, which are outlined on *FR* page 34541.