PREMIER TRANSFORMING HEALTHCARE TOGETHER®

December 12, 2019

Ms. Amy Bassano
Acting Director
Center for Medicare and Medicaid Innovation (CMMI)
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Submitted electronically to OCF@cms.hhs.gov

Re: Oncology Care First Model: Informal Request for Information

Dear Acting Director Bassano:

On behalf of the Premier healthcare alliance serving more than 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare, we appreciate the opportunity to comment on the Oncology Care First model request for information. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Premier runs one the largest population health collaboratives in the country, the Population Health Management Collaborative with more than 500 participating hospitals, in addition to an extensive Bundled Payment Collaborative with 120 participating facilities including participants in the Oncology Care model. Our comments primarily reflect the concerns of our hospitals and health systems, along with their employed and aligned independent physicians.

GENERAL COMMENTS

Premier supports CMS' effort to build upon the lessons and successes of the Oncology Care Model (OCM) through a successor alternative payment model (APM). Results from the first two years of the OCM program indicated that more than 85 percent of participants were able to lower total cost of care expenditures. Providers currently participating in OCM credit the model with enabling care redesign efforts in their oncology practices. However, we encourage CMS to make every effort to certify and expand CMMI models that are found to successfully improve care and reduce costs.

CMS has indicated there will be subsequent opportunities to provide input to CMS on the design of OCF prior to the finalization of the model. Premier welcomes the opportunity to provide feedback on future iterations prior to the release of the model. Further, we support CMS' intention of starting OCF on January 1, 2021 to ensure that current participants in OCM are not required to revert to fee-for-service payment before starting the OCF model.

PAYMENT METHODOLOGY

CMS describes two payment mechanisms within OCF: (1) a prospective monthly payment population and (2) total cost of care accountability for Medicare costs including drug costs during a six-month episode.

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Monthly Population Payment (MPP)

CMS describes paying OCF participants a prospective monthly population payment (MPP) for an assigned population of Medicare FFS beneficiaries with a cancer or cancer-related diagnosis. The MPP would be comprised of a management component (enhanced services, evaluation and management (E&M) services) and an administration component (drug administration, E&M payments to hospital outpatient departments as applicable). The MPP is structured similar to the Monthly Enhanced Oncology Services (MEOS) payment; however, it is paid prospectively (rather than billed) with other enhancements as described below. Generally, we appreciate the acknowledgement of the challenges that OCM participants have faced in separately billing the MEOS payment.

Beneficiary Attribution. The MPP expands upon the types of patients currently served in OCM by incorporating patients receiving oncology care management services. **We support the inclusion of patients receiving ongoing oncology-centered care management in the MPP** to expressly indicate that the care needs of this patient population are incorporated into care redesign efforts. CMS indicates that all Medicare FFS beneficiaries who receive an E&M service with a cancer or cancer-related diagnosis designated on the Medicare claim with a date of service during the performance period would be attributed to an OCF participant for purposes of the MPP payment. CMS notes in cases where an assigned beneficiary receives attributable services at two OCF participants, the beneficiary would be assigned to both for the purpose of the MPP calculation. **Premier supports permitting beneficiary assignment to multiple providers,** this could prove beneficial to providers operating in regions where there are substantial seasonal changes in population. We ask that CMS provide additional information on how MPP reconciliation will change when a beneficiary is assigned to multiple OCF participants.

Enhanced Services. The enhanced services component of the MPP will require physician group practice (PGP) participants to implement seven care redesign activities, five of which will be classified as Enhanced Services and supported through a supplemental per attributed beneficiary payment. Six of the seven activities are currently required in OCM, while adding a new requirement to gradually implement electronic patient-reported outcomes (ePROs). **Premier supports CMS' inclusion of the Enhanced Services to allow practices the opportunity to receive a prospective payment to finance investment in care redesign efforts**. It is essential to support participating providers in care redesign activities through a funding mechanism, especially as providers accept greater financial risk in APMs. Providers are expected to make expensive investments in non-billable services (health IT, care transitions, patient access to information, etc.) that will ultimately improve care and efficiency. However, it takes time to realize savings from care redesign.

Laboratory and Imaging Services. CMS indicates it is considering including additional services in the MPP, such as lab and imaging services. **We strongly oppose the inclusion of lab and imaging services in the MPP.** Currently, OCF participants are not capable of paying downstream providers nor is it cost-effective to outsource claims for these services to a third-party administrator. Similarly, if CMS includes lab and imaging in the MPP but continues to pay non-participating lab and imaging service providers separately, OCF participants would be subject to a significant reconciliation recoupment for those services. Adding lab and imaging services to the MPP would create unnecessary burden for OCF participants.

Risk Stratification. Using historical spending, trended forward based on non-OCF participants, CMS will create a median MPP. CMS will to take into account an OCF participant's patient volume and case mix and stratify the MPP by risk: (1) high risk patients (receiving chemotherapy) stratified by cancer type; (2) low risk patients (hormonal therapy only) stratified by cancer type and (3) no hormonal therapy or chemotherapy for any cancer type. **Premier supports the stratification of the MPP, pending**

additional information on payment amounts. We agree that it is appropriate to adjust the MPP based on the profile of the patient population served by the participating provider. We encourage CMS to adjust the MPP for acuity of the beneficiaries served by oncology practices and geographic differences as current payments for E&M and drug administration services are adjusted for geography.

Reconciliation. CMS will prospectively calculate the MPP by estimating the volume and case mix of patients that would be assigned to the OCF participant using the most recently available claims data. During the post-performance period reconciliation, CMS would trend the payment rate forward based on total Medicare payments to non-OCF PGPs and HOPDs for included services. CMS proposes to apply trended rates to the actual assigned population to account for changes in volume and case mix, but not to changes to volume and intensity of services. **Premier supports a retrospective reconciliation of the MPP payment, but we are concerned about the time lag between the historical period used to establish the MPP and the performance period**.

Practice populations can change substantially between a past performance period and the current period. For example, a large oncology practice associated with an academic medical center can often experience substantial clinician turnover. One member reported that it was not uncommon to lose four or five oncologists in a given year and that replacement hires are not necessarily analogous. For example, a departing specialist in breast cancer may be replaced by a clinician focusing on endocrine cancers. To account for this challenge, Premier recommends that CMS provide an estimate of the MPP at least 60 days prior to the performance period including breakouts based on service attributable to E&M services, drug administration and Enhanced Services, along with a list NPIs of physicians billing under the TIN for the baseline period. CMS could then allow providers to submit a formal request for an adjustment to their prospective MPP to CMS based on their current number of clinicians and expected case mix. This adjusted prospective MPP would still be reconciled against the actual patient population during post-performance period reconciliation to ensure that requested adjustments are justified based on actual experience.

CMS has yet to define the historical period they anticipate using to calculate the MPP payment. Premier recommends that CMS evaluate whether the MPP should be based on the same six-month period (i.e. January – June; July – December) for the preceding one or two years of available claims data. This analysis could indicate whether there is a difference in payment periods due to seasonal emigration patterns; however, effects may be limited due to the months included in the performance period.

Providers Included in the MPP. CMS proposes including all Medicare FFS beneficiaries who receive an E&M service at the participating PGP with a cancer or cancer-related diagnosis in the MPP payment calculation. After an episode is initiated with a participating physician, included services provided at a HOPD would result in assignment to that outpatient department as well. CMS indicates that a HOPD that provides chemotherapy or chemotherapy services for 25 percent or more of a PGP participant's attributed episodes will need to voluntarily participate in the model in a grouping with the PGP participant. HOPDs that provide chemotherapy or chemotherapy services for less than 25 percent of a PGP's attributed episodes would not need to join the model for the PGP to be eligible to participate, though the HOPD could opt to voluntarily participate. HOPD participants would receive the MPP rather than separate FFS payments for drug administration and E&M services for assigned beneficiaries.

CMS notes that a PGP will not be allowed to participate in OCF if a partner HOPD providing services for more than 25 percent of a PGP's episodes does not voluntarily participate. CMS does not provide information on the payment differences, if any, that will exist between the MPP for PGPs and for HOPDs. Premier appreciates the acknowledgement of the role of HOPDs as a care partner in oncology care and believes alignment between providers helps improve quality and care coordination. **CMS should ensure that the MPP payment reflects the cost of providing included services in HOPDs**. While this

requirement reflects the emphasis placed on provider alignment, CMS must ensure that reimbursement for HOPDs is sufficient to ensure that community-based PGP practices and partner aligned HOPDs join the model.

CMS requested comment on the ability of HOPDs and PGPs to operate as a grouping in the RFI. However, additional information on the concept is needed in order to provide comment. In principle, Premier appreciates that HOPDs will not otherwise be responsible for the implementation of participant redesign activities for physician practices, or accountable for total cost of care.

Performance Based Payment (PBP)

The performance-based payment (PBP) will institute total cost of care accountability for Medicare costs, including drug costs, incurred during a six-month episode of care. As in OCM, costs for Medicare Part A and B, certain Part D expenditures (Low-income Cost Sharing Subsidy Amount, 80 percent of the Gross Drug Cost above the Catastrophic threshold) will be included. Similar to OCM, the episode would be triggered by a Medicare beneficiary's receipt of a Part B or D chemotherapy drug, dependent on quality performance and costs relative to benchmark and target amounts. The novel therapy adjustment from OCM would be carried forward into OCF, and CMS is considering making the adjustment at the cancer type level to better reflect differences in therapy costs.

Total episode expenditures will be reconciled against a benchmark or target amount, with possibility of receiving a PBP or owing a PBP recoupment. The benchmark will be based on historical episode payments, trended forward, risk adjusted, and adjusted for participant-specific experience. CMS is evaluating whether to calculate and apply a trend factor separately in order to account for changes in spending between cancer types. CMS is also considering incorporating an adjustment to account for use for new drugs when PGP participant has a higher proportion of expenditures for approved oncology drugs than non-OCF PGPs.

Risk Adjustment by Cancer Type. **Premier strongly supports CMS' proposal of calculating the trend factor and novel therapy adjustment separately for each cancer type with sufficient volume**. As we have previously noted, cancer-type level adjustment is needed to account for the significant differences in cancer types and associated expenses. The adjustment would represent an enhancement on the OCM by ensuring oncology practices are not favored or disadvantaged based on the profile of their patient population and/or oncologist specialist type composition. For example, practices in OCM with a significant number of beneficiaries with metastatic breast cancer found it challenging to generate savings after Ibrance was introduced and adopted in clinical protocols. CMS was responsive to concerns from OCM participants and implemented an adjustment to partially account for these changes. Implementing cancer-type specific trend factors will assist in these types of cases and more accurately reflect changes between baseline and present practice, particularly in cases where a participant has a larger than average proportion of their patients in cancer types impacted by the introduction of an expensive therapeutic program.

The adjustment is also necessary to provide participants with more accurate payments for cancer types that may be extraordinarily expensive, but rare. The impact of even a single occurrence of a low volume, but expensive cancer, such as blood cancer, in a performance period can determine whether savings for a performance period are attainable. Premier members participating in OCM noted that without adjustment at the cancer type level, smaller practices may not be able to accept two-sided risk at any point in the OCF model.

CMS should also **explore additional ways to adjust the trend factor by cancer stage** using staging data collected from current OCM participants. Patient cost of care and intensity of services vary by stage

of treatment. By incorporating cancer stage, greater precision in payments could be achieved. CMS should also evaluate whether it is possible to incorporate toxicity and complexity of chemotherapy into adjustments for cancer type.

Adjusting for Clinical Best Practices. CMS should evaluate how to best account for indications for new drugs going to market or drugs approved for metastatic new line of cancer type. Adjustments should dovetail with clinical practice changes. Premier recommends retroactively adjusting benchmarks to ensure analogous comparisons between the benchmark and expenditures in the performance period to account for rapidly changing clinical practice guidelines.

Inclusion of Part D Drug Costs. The inclusion of drug costs in the PBP payment creates significant challenges in controlling costs due to the high variable cost and the elevated expense of new oncology therapies and biologics. Spending on cancer drugs in the United States has more than doubled since 2013 and reached almost $57 billion in 2018, with 64 percent of the growth from the use of drugs launched within the past five years.[1] In 2018 alone, spending on cancer medicines grew by 15.9 percent.[2] While controlling spending growth for oncology drugs is a desirable policy goal, CMS must ensure that providers that are financially at-risk are not harmed due to factors that are outside of their control or for providing care that is clinically appropriate.

Extension of Novel Therapy Adjustment. CMS proposes to adopt the novel therapy adjustment currently used in OCM for the OCF model. In OCM, the adjustment lasts for two years and compares the percentage of average episode expenditures for novel therapy for the participant to average expenditures for non-OCM practices. However, the impact of a novel therapy introduction extends beyond two years. Spending growth in oncology care is currently driven through continued volume growth for launches from 3–5 years ago, along with the continued introduction of newer brands.[3] Premier recommends that **CMS evaluate the impact of extending the novel therapy adjustment from two years to four years** to account for continued volume growth for drugs that have been introduced more than two years ago, but continue to experience significant volume growth.

Stop-loss Limits. CMS previously instituted a 20 percent stop-loss/stop-gain policy for two-sided risk in the OCM but did not include discussion of stop-loss protection in the RFI. Providers at financial risk require financial protections to ensure that outliers do not jeopardize a provider's ability to continue operating and delivering patient care. Premier recommends that **CMS provide an option for stop-loss protection to providers in the OCF model given the high variability of costs for oncology patients.**

Attribution. CMS proposes attributing beneficiaries to PBPs based on whom provides the episode-initiating chemotherapy if the PGP also bills at least 25 percent of the cancer-related E&M services. CMS indicates that attribution would revert to being based on plurality of services, if either the initial PGP does not meet the minimum 25 percent of services or if episode-initiating chemotherapy is provided at a HOPD. Premier supports additional attribution criteria, including the addition of precedence for the physician initiating chemotherapy treatment. However, we recommend **CMS align the attribution approaches for PGPs and HOPDs, allow physicians ordering chemotherapy initiated in a HOPD to retain credit for the episode if the physician in the HOPD provides 25 percent of services.** Creating different criteria for episodes initiated in a HOPD runs counter to the goals of provider alignment.

Premier recommends that CMS evaluate attribution of patients to the physician that is managing their oncology care. Multispecialty PGPs have experienced inadvertent attribution of patients in OCM

[1] IQVIA. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncology-trends-2019.pdf?_=1574269116600
[2] Ibid.
[3] Ibid.

when a patient receiving chemotherapy from an unaffiliated practice receives care from another physician within the participant's TIN. We believe the 25 percent of E&M services will mitigate this issue; however, CMS could explore adding a claim modifier to indicate that a physician is currently managing an OCF patient's oncology care.

Despite the proposed additional criteria, the new guideline would do little to assist participants in understanding whether a patient is likely to be attributed to their practice. For example, providers have a record of a patient receiving a chemotherapy infusion, which is one triggering event for an OCM episode. However, the other triggering event in OCM is when a patient fills a prescription for an initiating oral therapy, yet practices do not always have visibility into when or if this occurs. OCM participants have also noted that providers, particularly those practicing in regions with significant seasonal emigration, may provide a substantial amount of a patient's services but fail to receive attribution of a patient. These challenges are compounded by providers receiving data only on a quarterly basis. **Premier requests that CMS provide data to participants on a monthly** basis through reports, with the option of receiving data via a Claim and Claim Line Feed, to assist practices in assessing beneficiary alignment.

Risk Tracks. CMS proposed three PBP risk tracks: 1) a one-sided risk track available for the first two performance periods (i.e. 12 months) of OCF that is available only to non-OCM participants; 2) a two-sided risk track with a relatively limited amount of risk; 3) a two-side risk track with greater potential up and downside risk. CMS has noted their intention that both two-sided risk tracks would meet the nominal risk standard for the Quality Payment Program (QPP) but has not indicated with specificity the level of risk they intend to assign to each risk track. Premier supports the ability of providers to select a level of risk most appropriate for their practice, as providers have varying levels of experience and capacity to handle financial risk.

Premier appreciates that CMS continues to create pathways to risk adoption across payment models. This allows providers to enter at a risk level that is most appropriate for their practice. We recommend the following changes to the risk tracks:

- **Extend the amount of time allowed in the no risk track to at least two years.** As illustrated by providers participating in CMS models thus far, it often takes at least three years for providers to begin capturing financial improvements as a result of care redesign efforts. An inherent challenge in the model design is that the Enhanced Services payment is not included in the benchmark. This requires participants to offset the enhanced payment for the additional services through reduced spending on care in order to break even under the model. Providing additional time in a no risk track mitigates this concern. We believe CMS should allow at least two years in the no risk track, similar to the amount of time allowed in the no risk tracks of the Medicare Shared Savings Program (MSSP). Similarly, CMS should consider allowing certain practices (i.e. those with savings and high quality) to continue in a no risk track for additional years.
- **Allow OCM practices to enter the no risk track.** There are significant changes between OCM and OCF, such as the beneficiaries included in the MPP and the MPP payment structure. Many OCM practices have been able to generate savings in the program and remain in one-sided risk and thus have not had prior experience in two-sided risk. While participants can rely on their OCM experience, they will still need time to acclimate to the model. The ability to have a ramp-up period to two-sided risk will encourage these PGPs, especially smaller practices, to apply and continue in the OCF model. To encourage a continued progression to risk, CMS could reduce the amount of time current OCM participants can remain in a no risk track. For example, one year instead of two years.

- **Create a lower risk track that does not meet the Advanced Alternative Payment Model (AAPM) nominal risk standard.** Similar to MSSP, we encourage CMS to create a minimal risk

track. This would allow participants to gain experience with downside risk prior to participating in a risk track that meets the AAPM nominal risk threshold.

- **Eliminate a higher risk track that exceeds the AAPM nominal risk standard.** We do not believe participants will have interest in a risk track that exceeds the nominal risk standard. Premier members participating in OCM did not indicate interest in pursuing a model with risk in excess of the nominal risk standard. In lieu of two risk tracks that meet the nominal risk standard, we suggest two risk tracks - one that meets the standard and one with lower risk.

Discount. CMS proposes a discount of 3 to 4 percent of baseline expenditures in the RFI. We assume that the OCF model will operate as a total cost of care model, as OCM is structured. In this case, the nominal risk standard would be met through shared savings/losses and **the discount for OCF should be reduced and made comparable to other similar models,** such as MSSP (2 percent) or OCM (2.5 percent).

Reconciliation. CMS proposes that reconciliation will occur on a semi-annual basis, after all episodes initiated during a performance period end and allowing for a one-month run out of claims. CMS will also perform one subsequent true-up reconciliation one year after initial reconciliation. Premier supports a single true up reconciliation that allows for complete claims run-out and final adjustments. The single true up will be less burdensome to providers and to CMS than the two true up reconciliations performed in OCM.

CARE REDESIGN, QUALITY, REPORTING AND OVERLAP

*Mandatory Care Redesign Activities***. Premier supports including seven PGP participant redesign activities in OCF,** five of which are defined as Enhanced Services. The activities reflect six activities that are currently incorporated into the OCM program and the addition of a requirement to report electronic patient-reported outcomes (ePROs).

Additional information is needed on the PROs under consideration. We understand that measure development requires broad information to determine the most appropriate elements for inclusion in a measure. PROs may require additional effort if the measure requires coordination between hospitals and physicians, or coordination of pre and post episodes PROs. However, excessively large requests for data may discourage reporting. For example, Premier participants in the Comprehensive Care for Joint Replacement (CJR) model have reported that the extensive requirements associated with reporting the voluntary patient reported outcome measure is not worth the additional points awarded in the quality score. **We recommend that CMS assess the cost of reporting the ePROs selected and ensure the Enhanced Services payment in the MPP is sufficient to assist practices in establishing and supporting ePRO reporting.** Further, CMS should establish requirements for successful data collection that allow sufficient data collection for clinical and measure development but does not penalize participants reporting in good faith if their ePRO submission fails to meet comprehensive requirements. We also support flexibility in reporting, including permitting providers choice of ePRO reporting instrument.

Quality. CMS indicates that OCF will use the same quality measures that are used in OCM, as of performance period six. As in OCM, a performance multiplier will be applied. The performance multiplier will sum each PGP participant's scores on quality measures and cross walk the aggregate score to a performance multiplier. The resulting multiplier will apply to the PBP or PBP recoupment amount to allow providers with high quality performance results to attain either a higher PBP or lower PBP recoupments than those with lower quality scores. **Premier appreciates CMS' responsiveness to participant**

concerns and adjusting the quality measure set accordingly during the OCM. We support carrying forward the quality scores used in OCM PP6 and thereafter into the OCF program. Additionally, CMS and ONC should establish core clinical data elements for oncology care and measurement and adopt standards for capturing and exchanging the data as part of routine care and business transactions.

Data Collection and Sharing. CMS indicates that the OCF program will utilize the same data sharing and collection strategy used in OCM. However, the current staging and clinical data reporting process is time-consuming. Practices participating in OCM note they presently report the same data elements on a subset of their beneficiaries to other registries, creating reporting redundancies. Despite the challenges in reporting this information, participants find this data valuable and think the information should be used to adjust the MPP. **Premier recommends that CMS enable the OCM registry to pull data from other relevant registries for applicable patients to ensure consistency in reporting and lower provider burden.**

Model Overlap. CMS does not outline a model overlap policy in the RFI. **Premier encourages CMS to develop comprehensive overlap and precedence guidance prior to model launch.** For example, we presume that OCF participants would not be permitted to participate in other total cost of care models. Participants require clarity as soon as possible, especially as providers evaluate participation in multiple APMs scheduled to start in 2021.

CONCLUSION

The Premier healthcare alliance supports CMS' efforts to transform healthcare delivery and appreciates the opportunity to share feedback on the proposed design of the OCF model. If you have any questions regarding these comments or need more information, please contact Aisha Pittman, vice president of policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance