COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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March 16, 2018

Anand Shah, MD
Chief Medical Officer, Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Shah:

On behalf of the Community Oncology Alliance (COA), we are submitting our concerns regarding the Oncology Care Model (OCM) to the leadership at the Center for Medicare & Medicaid Innovation (CMMI). As you know, COA is the leading cancer organization championing the OCM as witnessed by the significant resources we have dedicated to the effort and by having over 80% of the OCM participants (accounting for an estimated 90+% of the OCM patients) in a cooperative learning and information exchange network. We want to underscore the substantial commitment we are making to ensure the success of the OCM – *a success that we believe is very much in doubt.*

With that said, now that the first Reconciliation Reports have been released, we have some pressing and key concerns, summarized as follows:

1. The OCM in its current form is methodologically flawed with respect to predicted episode pricing, including significant deficits related to:
    a. Risk adjustment for breast, prostate, and bladder cancers;
    b. attribution and MEOS claims submission; and the
    c. approach towards novel therapies

2. Complexity in attribution and delays in receiving data regarding attribution are leading to major financial, operational, and clinical issues for participants. These issues are heading towards large recoupment amounts that will need to be paid back to the Centers for Medicare and Medicaid Services (CMS) after the first true-up of MEOS claims, skewed reconciliation results, and problems in quality measurement and in the data reported to the OCM clinical registry. Planning for MEOS recoupments is especially creating financial hardships for participants given cash flow dynamics, complicating continued participation for practices.

3. Greater flexibility is needed regarding allowed timeframes given the complexity of the program, notably related to attribution and contestation submission. A high-priority situation where greater flexibility is needed is the 12-month window for revising submitted MEOS claims, particularly due to the extended length of time before participants received their official attribution lists and attribution related data.

4. The approach towards novel therapies requires special, immediate attention and modification. The current methodology relating to novel therapies opens up the risk of creating perverse incentives for using inferior drug treatments that could adversely impact patient care. This is especially the case given other issues related to episode pricing. ***We note that we are extremely concerned, under any circumstances, about any incentives or pressures to lower costs by forcing the use of clearly inferior treatments.***

5. Total transparency by CMMI is essential to enable full reproduction of the OCM methodology by participants. This includes clear disclosure of all weights and variables needed to reproduce the methodology in full. Confusion about important variables, such as the trend factor and inconsistencies in implementation of the novel therapy adjustment, are creating an environment of chaos, which will ultimately result in model failure. ***In short, how can practices attempt to increase quality and cost efficiencies if they do not understand the "grading" system?***

6. For the performance multiplier related to OCM measures one (1) to three (3), the distribution of cut points separating levels of performance is very narrow. While these cut points are empirically motivated, the limited range introduces disconcerting sources of error and sensitivity to random effects.

7. Geographic adjustments to episode costs are done at the level of the patient, rather than where services are provided. This distorts episode costs for patients who receive cancer care in a different Hospital Referral Region (HRR) than their primary residence.

8. Learning communities created by the OCM vendor have to date been far too one-way only, with very little transparency and two-way communication.

On behalf of the COA Board of Directors, our internal OCM/OCM 2.0 team, our Oncology Payment Reform Committee, and the OCM participants in our network, we cannot underscore enough our very serious concern about the viability of the OCM. ***On its current path, the OCM is simply not a realistic, viable model for all Medicare Part B oncology payments, which is the underlying purpose of implementing this demonstration project.***

We sent you a memo (attached) dated February 22, 2018 about our concerns relating to novel therapies. Now, with the release of the Reconciliation Reports, we are convinced that the time for very serious modifications to the OCM are long overdue. We know of several OCM participants considering dropping out of the program right now. So many participants are frustrated and bordering on angry. We do not want this to become a watershed event.

We welcome an opportunity to have a much more detailed conversation about our concerns. Please note that we have resisted making any comments to the press, now that the Reconciliation Reports have been released, in the spirit of cooperation and, hopefully, discussion with CMMI.

What follows are some more detailed points relating to the issues/problems we summarized above.

Methodological Issues in Price Prediction Related to Risk Adjustment

Since Reconciliation Reports were released, we have become aware that a number of participants, particularly large ones, did not achieve any performance-based payment (PBP). We are deeply concerned that the delay in implementing the changes in prostate and bladder cancer risk adjustments (these known issues were discovered early on but were not applied until the third (3rd) performance period), as well as growing concerns around risk adjustment in breast cancer (as outlined to you in the attached memo), are significant contributors to this failure to achieve savings.

We note that an informal survey of eighty-six (86) OCM participants, including the largest OCM practices/facilities, found that only sixteen (16) achieved any positive savings. Although, this is sixteen percent (16%) of the participants, our rough estimate is that it is only about ten percent (10%) of the activity as measured by patients. Additionally, some of the most active and successful practices that have participated in other Medicare (COME HOME) and private insurer (e.g., Aetna, United Healthcare, Priority, others) models/pilots actually performed very poorly in terms of OCM savings.

The risk adjustment issues are causing the inappropriate loss of potential shared savings and are the foundational reasons for why: 1) so few participants achieved shared savings; and 2) those practices that did achieve shared savings were under target by comparatively small sums when compared to how far over target most practices were.

In addition, flaws in the risk adjustment models for the cancers referenced above are leading to such large-scale problems that it is likely that all of the coefficient weights in the OCM prediction model for episode costs are adversely affected, diminishing the validity of pricing globally. Together, these issues all but preclude making meaningful inferences about participant performance in performance period one (1).

We strongly suggest that the known issues in prostate and bladder cancer and errors in the breast cancer risk adjustment be addressed immediately. Financial models used to predict episode costs from the baseline period and performance period one (1) should be rerun for more accurate weight variables. Reconciliation results for performance period one (1) should be rerun to reflect the corrected risk adjustment. It simply is not consistent with clinical medicine to label existing patients as low risk when that is not the case.

These significant problems in pricing, their impact on success in the program, and the ambiguity they create in understanding actual performance means that participants will have fewer opportunities than initially anticipated to learn how to substantively improve performance from the first reconciliation results. This need for adjusting time frames is further emphasized by a statement in the Participation Agreement: "*If the Practice is a Non-Pooled OCM Participant, CMS may terminate this Agreement if the Practice does not earn a PBP by the time of initial Reconciliation of the fourth Performance Period."* OCM participants are currently in the fourth (4^{th}) performance period and are frantically trying to understand and respond to these reports. There are only three and a half (3.5) months remaining in the fourth (4^{th}) performance period. The ability and time realistically and practically to respond to these reports in order to implement practice changes that can lead to a positive PBP is very limited, at best. In addition, CMS will need time to review these recommendations, resolve the known faults, and modify the program accordingly. ***Therefore, we strongly recommend that CMS not remove participants from the OCM until after they receive their Reconciliation Reports for the sixth (6^{th}) performance period.***

Attribution and MEOS Claims Submission, Quality Measurement, and Clinical Data Submission

Numerous challenges confront OCM participants related to attribution, ***particularly related to oral triggers***. Many practices face large recoupments of MEOS funds related to complications of attribution. Gaps in attribution are likely leading to lost shared savings as delays in beneficiary identification diminishes the opportunity for care management. Recoupments create financial stressors, especially with respect to cash flow and availability of funds.

These issues are heightened by the lengthy delays prior to practices receiving official attribution lists. The burden is further magnified by the twelve (12) month time window available to modify MEOS claims. Given how long it has taken CMMI to deliver official attribution reports, inadequate time is available to modify MEOS claims fully when needed.

CMMI ideally should provide definitive attribution lists early on in performance periods. If that is not feasible, at a minimum, the twelve (12) month MEOS modification period should be extended and the OCM claims files should be provided to OCM participants on a monthly basis so that they can project attribution accurately, ***particularly for patients on orals***.

Novel Therapies

In addition to the issues raised in our recent memo to you (attached to this letter), we are also concerned about problems in the implementation of the novel therapy adjustment, particularly related to the very high threshold required before the novel therapy adjustment comes to the fore, and then only at a rate of eighty percent (80%), rather than full cost adjustment. Given the limited variance at the upper end among many OCM participants, the concern holds that misaligned incentives may emerge that could adversely impact patient care. Again, greater transparency and clarification is essential.

Quality Measures

The three (3) most prominent PBP measures around risk adjusted hospitalizations, risk adjusted ED visits, and hospice have very narrow cut points between quartiles, creating a disproportionate impact on results. In addition, the

first two (2) risk adjustment measures have a separate risk adjustment methodology from the episode pricing, which creates more confusion and methodological misalignment. ***We strongly suggest more granularity in measurement, moving away from a quartile method with narrow cut points and changing risk adjustment approaches to be more explicit and easier to understand.***

Enhancing Transparency

We believe that the OCM team is doing its best given the complexity of one of the first ambulatory specialty payment models that CMMI has fielded. However, greater transparency is clearly needed, especially relating to the specific weights and variables essential to OCM participants understanding the model, their performance, and how CMMI arrived at its results. Given the complexity of OCM as a model, being able to simulate the methodology in full is critical to deepening understanding of the model by making payment model design more concrete.

Additional light is especially needed regarding the trend factor and experience adjustments so that practices can better understand how these issues impact their performance. Lack of transparency in this area is especially troubling. We've counted four (4) distinct sets of coefficients that are used in the OCM prediction model for different analyses, but OCM has only published one set: the coefficients that, together with the experience adjustment, constitute an episode's baseline price. At least three (3) sets of coefficients have not been made available, which go into the calculation of the trend factor and experience adjustors themselves. The variance around the weighting for HRRs is another example of unnecessary opacity. Our team noted that in the last two (2) OCM learning sessions and webinars there were requests for such factors to be revealed, but the answers were not provided and to date no follow up has been acknowledged.

In a similar vein, releasing OCM claims data at a faster rate – monthly rather than quarterly – is critical to deepening understanding of the model and increasing the probability of participants reaching shared savings. Further, there are currently significant gaps between the patients included in quarterly feedback data and OCM-eligible patients that participants include in their data submissions to CMMI. Giving participants further information about patients who they are treating is necessary to improve attribution by CMMI and patient identification by practices.

Our extensive work with these models on the private insurer side has revealed key learnings. Practices need to clearly understand how they are being graded – what they are doing right and what needs to be improved. After all, the OCM should not be focused on an operational grade. It should be about practice transformation. That starts with a focus on the patient and changing clinical and operational processes to deliver the highest quality cancer care in the most cost-efficient manner. That change, and continuous improvement, is only possible with timely, accurate, and meaningful feedback, including "grading" that is totally transparent and understandable. Unfortunately, the OCM as it is currently being implemented is sorely lacking along those lines.

Geographic Adjustments

In an effort to adjust prices to reflect differences in health care costs in different markets, the OCM prediction model uses weights associated with each HRR. However, episodes are assigned to the patient's primary residence zip code, which may not coincide with the primary point of service. We urge OCM to adjust the model so that prices reflect the HRR for the attributed practice/facility, which would more accurately reflect differences in the cost of care for patients who travel or maintain multiple residences. This change would be easy to implement and would improve precision in controlling for geographic disparity of health care costs.

Communication

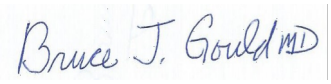
The OCM team is trying to be responsive and we sincerely appreciate the interaction with the team, especially as led by Lara Strawbridge. However, there are so few opportunities to engage with the team in real time that it reinforces a pervasive fear that nothing will change from a program perspective. Additionally, there is also a palpable frustration that care transformation, while costly and labor-intensive, does not correlate at all to PBP savings. As stated previously, the most experienced practices with oncology payment reform models — that have truly and dramatically transformed their practices – are among the least successful and most frustrated. On that front, our team

is very concerned that the weighting of these practices essentially competing against themselves is an exercise in futility given how much they have already transformed their practices.

It is our desire to work closely with CMMI on solutions, but to do so we must move beyond webinars that are too crowded for real dialogue and advance into serious and immediate policy changes that can improve the program. ***On its current course, we are concerned that the OCM will fail, both as a demonstration project and as a model that can realistically transform the Medicare Part B payment system.***

Our recommendation is to convene a meeting ASAP with our team and a sampling of the OCM participants. ***We now have arrived at a serious and critical juncture. Real action is needed!***

Sincerely,



Bruce Gould
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Memorandum

February 22, 2018

To: Centers for Medicare & Medicaid Innovation (CMMI)
From: Community Oncology Alliance (COA)
Re: Programmatic Concerns Related to the Oncology Care Model (OCM), with a Focus on Therapeutics

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Background

The pace of innovation in oncology therapeutics creates significant challenges for the design and implementation of value-based payment models such as the Oncology Care Model (OCM). New classes of treatments, such as immunotherapies, have dramatically changed the therapeutic landscape over very compressed timeframes. How to account for the impact these agents have on expected resource utilization, creates complex dynamics involving clinical care, organizational change, methodology, and policy.

This memo highlights key emerging issues related to novel therapies, as well as common therapeutic classes and the OCM. It draws on the breadth of the Community Oncology Alliance's (COA) experience supporting over 150 OCM practices from around the country, our policy engagement with the Center for Medicare & Medicaid Innovation (CMMI), as well as other payers involved with OCM, and our work defining the future of payment model design in cancer (the "OCM 2.0" as we have referenced in previous discussions).

We have tried to highlight issues and potential solutions, acknowledging that solutions are not easy, but in our work, we have continued to see great enthusiasm for the program; however, there are significant concerns that inhibit moving to 2-sided risk, as well as issues around long-term participation. Unfortunately, we have been in touch with practices that have left, or are considering leaving, the program due to some of these issues.

Issue #1: Attribution and Novel Therapies

Many newer classes of antineoplastics are orally available and complex to take. Oral agents have proven especially challenging for practices to account for in their OCM episode attribution and in the related MEOS billing. As a treatment-based model, receipt of the agent is a central part of the OCM trigger methodology. As orals are reimbursed out of the pharmacy benefit through third-party Part D plans, information management, and tracking has proven extremely complex for OCM practices.

Currently, COA is seeing gaps in attribution at practices on the range of anywhere from 15-40 percent error rates. One of the leading causes of these errors is due to oral agents and the OCM methodology. Many of the patients on novel oral agents are the ones who are most in need of advanced care coordination services. These are also proving to be among the most challenging patients for practices to identify in a valid fashion per the OCM methodology.

The financial risk and implications for practices from this complexity is also significant. Gaps in attribution are creating situations in which practices are facing very large recoupments back to CMS.

These recoupments are often driven by the practice's administrative mistakes related to information flow and management rather than the patient not truly being cared for by the OCM practice as the primary provider. We commend the OCM team for trying to work with practices and offering an opportunity to clarify attribution, but unfortunately the time window (12 months) to close the gap is limiting due to the delays in data, etc.

Possible solutions:

- Potentially expand the window of time for MEOS claims submissions
- Provide official attribution lists from CMMI much faster than currently provided
- Increase resources available so that claims data can be sent out on a monthly basis rather than quarterly
- Understand how existing therapies with novel ***indications*** are handled within OCM

Issue #2: Risk Adjustment and Novel Therapies – Current Problems in Target Price Setting for Breast Cancer

COA strongly supports CMMI's adoption of risk adjustment in OCM. Assessing differences in expected resource utilization in a specialty such as cancer, in which disease intensity can vary so greatly, is critical to rational payment policy. Given the complexity of this issue, it was expected that difficulties would arise with risk adjustment and improvements in the model's risk adjustment methodology would likely be needed.

COA has been informed through claims work done by Tuple Health (a partner in our OCM efforts) that there is a significant flaw in the OCM risk adjustment model for breast cancer related to emerging therapies (this issue was identified through detailed claims analyses conducted by Tuple Health, which has also been discussed with OCM team members).

Currently, three (3) OCM cancers are divided into "low risk" and "high risk" cohorts: breast, prostate, and bladder. In each target, prices for the low risk vs. high risk groups will be set very differently, reflecting differences in expected resource intensity. In each instance, CMMI is drawing inferences around clinical risk from the type of treatment patients are receiving. For breast cancer, the key distinction in the OCM methodology is to separate out patients who are in the lower intensity phase of their treatment - primarily patients who are on long-term adjuvant endocrine therapy.

Through detailed analysis of OCM claims, we discovered an anomalous set of episodes in which large discrepancies existed between the baseline data and CMMI's projected episodes' prices and actual costs. Further investigation showed discrepancies between Tuple Health's risk adjustment for breast cancer and CMMI's. When delving into these differences further, Tuple Health determined that the CMMI implementation of its variable for "low risk" breast cancer was defined by patients having only Part D claims in an episode.

While this implementation of "low risk" breast cancer may have been sufficient to identify patients on long-term endocrine therapy several years ago, it is no longer sufficient due to the emergence of novel classes of therapies, the CDK 4/6 inhibitors in particular. The implications of this are stark. **The projected target prices for these episodes don't even cover Medicare's allowed payment amount for the agent itself (disregarding the cost of all other care**). For example, episodes in which a patient is on a CDK4/6 inhibitor such as palbociclib + an aromatase inhibitor will only have Part D claims and in turn be designated as "low risk." Those types of episodes will in turn have projected prices estimated at ~$6,000, *while the actual costs may be around $40,000*.

We estimate this misclassification issue in the breast cancer risk adjuster will impact ~7-8 percent of all breast cancer episodes nationally. CMMI has had experience with correcting something that was similar in GU cancers and we hope that such a precedent could be helpful to also solve the current issue. Given the magnitude of this issue, unless newer classes of orals are modeled correctly, the financial shortfalls will likely cause a crisis in confidence among OCM participants and lead to practices dropping out.

Potential Solution:

- Much like the solution achieved in GU cancers, consider modifying the definition of "low risk" and "high risk" to be clinically aligned rather than by the presence or absence of a Part D claim

Issue #3: The OCM Novel Therapy Adjustment Methodology – Novel Therapies on the Individual Agent Level vs. Novel Therapies on the Group Level

The current OCM methodology related to novel therapies involves adding together all of the costs a practice incurs on novel agents as a group, calculating the proportion of a practice's total costs spent on novel therapies, and comparing that aggregated proportion to non-OCM practices nationally. If the practice spends more on novel agents as a proportion of its total spending than non-OCM practices, its total target price is adjusted upwards by 80 percent of the difference in proportion.

Adjusting for novel therapies as a group rather than on an individual agent-by-agent basis creates significant risk for practices. A practice may only use a handful of all the agents CMMI has designated as novel while not using other agents designated as novel. This means that the practice's total spending on novel agents as a class may not be higher than average even though its use of specific agents may be far higher than average. This, in turn will likely lead to that practice being significantly over target for episodes in which it uses that agent.,

In aggregate, this could create a strong disincentive for practices to adopt new therapies due to the associated risk in target price setting vs. actual costs. This risk will likely be hardest felt by small to medium sized practices.

Potential Solution:

- Consider a sensitivity analysis that would analyze the effects of looking at the top set of novel agents prescribed versus the total/aggregated costs

Issue #4: Novel Therapies and Pharmacological Class

In the OCM methodology, agents are considered novel for a period of two (2) years after receiving an FDA indication. The efficacy of many novel therapies, however, relates to the effect that class of drugs has; e.g. PD1 inhibitors.

The first drug in a class of drugs may lose its designation as a novel therapy in the OCM methodology while agents in that class that emerge later (e.g. "me too" agents and agents that really act like biosimilars) will still be designated as a novel. This is particularly true in the early years of the OCM model.

This gap is problematic as it creates a potential for unintended consequence in influencing treatment decisions and formulary policy at practices.

Potential Solution:

- Consider excluding the class, as well as the individual agent, similar to what CMMI has declared around CAR-T therapies or consider different lengths of time for the exclusion

Issue #5: Expansion of Clinical Data Reporting & Workload

OCM currently requires submission of significant clinical data. Much of this data has to be manually collected, standardized, and entered by practices creating a significant burden and diverting resources from patient care to program administration.

Novel therapies are often targeted agents and used in response to specific findings; e.g. results of a diagnostic test. As novel therapies continue to expand, the risk exists for the burden of data submission and reporting to continue to grow more and more difficult for practices to manage.

Potential Solutions:

- Restrict/limit clinical data reporting to specific cancers
- Work with practices to understand how to stage/implement registry in phases that are more administratively manageable

Issue #6: Timeliness of Claims Data & Novel Therapies

Given the costs of newer agents, rationalizing the use of novel therapies will likely be a key foundational aspect to performance in OCM. This requires close tracking of utilization.

To manage cost and utilization of novel therapies, practices need to receive claims data in a timely fashion. Without that data, managing the trend and impact of agents is very challenging, particularly given the pace of innovation in treatment. New indications are emerging every month. Many of the new agents are orals for which only claims data can provide important features of utilization. Currently, OCM claims data is provided only on a quarterly basis. Claims data needs to be provided on a monthly basis (the time frame it's provided in the BPCI model) in order to rationalize novel therapy utilization.

Potential Solution:

- Mimic the BPCI monthly claims feed model; this would also help with attribution issues