Monday, August 12, 2019

Submitted electronically to: http://www.regulations.gov

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program: Reducing Administrative Burden to Put Patients over Paperwork: CMS-6082-NC

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the Medicare Program: Reducing Administrative Burden to Put Patients over Paperwork (CMS-6082-NC).

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices and physicians to advocate for public policies to support patients with cancer and their provision of care in the most effective and cost-efficient ways. At the core of our mission is the transformation of the health care system focusing on a patient centered model of care.

As an organization, COA is appreciative of the opportunity to make comments on this RFI. It is clear that over the years, administrative burden has become an increasing issue in practices and an impediment to the care of patients with cancer. We have polled our membership and intend in this letter to enumerate some of the administrative paperwork burdens currently encountered by our providers and their community practices and offer some potential solutions.

In polling COA members, several themes of administrative burden were consistently discovered. These include:

- Redundancy of documentation;
- Increasing bureaucracy encountered with pre-certification processes with an emphasis on Medicare Advantage plans;
• Inefficiencies of use of current certified Electronic Health Records (EHRs); and
• Value-based models of care asking for efficiencies yet requiring more documentation than ever in the past.

We intend to comment on each of these areas in further detail in this letter.

**Redundancy of Documentation:**

One of the most challenging things seen has been the growth of measuring metrics through MIPS and QPP that increases the burden without any clear evidence that it helps patients. There is talk about the challenging administrative burden and high costs of care, but it is not appreciated that a large part of that is in managing increasing administrative demands for documentation and especially for documenting quality metrics. It is not at all clear that MIPS or the QPP improves quality of care. In fact, it may diminish quality as the time spent documenting is triple or quadruple, diminishing the time spent in the room with patients. CMS is considering changes in the current E&M documentation requirements. The current E&M standards were created before the widespread adoption of EHRs in clinical practice. These standards are ripe for reform. Vital and necessary streamlining of documentation and reporting should not lead to lower reimbursements for physician services, however. There has been a faulty notion that documentation and reporting activities have comprised the bulk of activity within cancer care patient visits. In fact, that is not the case. We commend CMS for walking back the proposed collapsing and combining of rates for some E&M services in the proposed 2020 MPFS.

As an example, one physician wrote: “I see a patient that smokes. I discuss with them smoking cessation. I may refer them to written material. I then have to check the box in my EMR (Electronic Medical Record), dictate that I did it in my note, sign off on a separate compliance note, and order a referral for smoking cessation class... all in addition to managing the patient on their cancer directed therapy.”

Another example includes: “I see a patient in pain. I ask about the pain - where it is, how severe, exacerbating and alleviating features, and suggest control measures. I then write scripts (and check the physician monitoring program in my state to make sure they are not an opioid abuser, and document I did so), document their pain level and my intervention in the EMR in a check box, dictate in my note, my assessment and plan for their pain, order a referral if indicated, and sign off on the compliance documentation all the while managing the patient who has also had toxicities of treatment and may require changes in cancer directed therapy.”

As more and more “value” metrics are added to practices, the amount of time in the day has not increased. Documentation processes are not necessarily considered in deriving such metrics, and the redundancy of competing documentation requirements from multiple stakeholders is the antipathy of “putting patients over paperwork”.

**Recommendation:**

• In an era of “value-based cancer care”, documentation of quality metrics should be streamlined. The burden of documenting such metrics should be strongly considered in the selection of metrics for value-based programs so that the burden of documentation is not out of proportion to the importance of that metric. Documentation should be easily accomplished through an EHR and should only be required once per patient encounter. State and Federal stakeholders should try to have similar requirements so that documentation is simplified. The goal of all quality metrics should be increasing the quality of patient care and redundant “documentation” should be eliminated to achieve this goal.
It is important to ensure that various activities, measures and requirements under the Quality Payment Program (QPP) are not duplicative with what providers are expected to do under other alternative payment programs. To the extent possible, CMS should ensure that activities and measures that do overlap, do not require further documentation. Also, the focus should be on measures that improve patient outcomes and promote high-quality care instead of focusing on processes. As shown in the examples above, the process measures and requirements that physicians are subjected to today only have a tangential link to cancer care and disease management.

- The same approach should be taken for all medical documentation, including all recent requirements for opioid prescribing. Single notations in one part of a medical record should suffice rather than having to record the same data in multiple ways simply to be compliant with regulatory documentation requirements. As an example, in the proposed 2020 MPFS there is a proposal to allow attending physicians to review and verify notes made by other physicians, residents, nurses, medical students and other members of a patient’s care team rather than to require them to re-document in a duplicative and redundant note. We support broad implementation of such common sense approaches.

**Medicare Advantage Plan Pre-Certification:**

In polling our membership, pre-certification processes for imaging and therapies on both the commercial insurance side and with Medicare Advantage plans is the **number one** identified area of overwhelming dissatisfaction with paperwork over patients. The amount of time being spent in doing this work by physicians, physician extenders and office personnel is staggering.

One practice described that 80% of the pre-certification work done in their office was for one Medicare Advantage plan that serviced 15% of the patients their practice sees. Another has pointed out that when the pre-certification processes are completed, including time required for peer-to-peer reviews, that less than 2% of requests are ever turned down. Hours upon hours of time are exerted by practices in doing pre-certification and the volumes and aggressiveness of the processes are seemingly highest with many Medicare Advantage plans, especially smaller local plans. Moreover, often the decision maker in the Medicare Advantage plan is not an oncologist and is unqualified to actually determine what is appropriate care.

Insurance companies and Medicare Advantage plans keep data on providers and know who abusers of overutilization of imaging or novel off pathway treatments are. Rather than focusing on those few players, all physicians and their patients are subjected to processes that are costly and delay treatments, which is frankly aggravating to conscientious providers and adds precious time to already stressed days of providing cancer care to Medicare patients. All this is despite personal track records of being providers who do things the right way.

Pathway management has become a standard in the treatment of oncology care. Most oncologists follow pathways that are peer reviewed. For patients being treated to the standard of care on treatment pathways, it remains ludicrous that pre-certification should be required beyond it being clear that patients are being treated in such a fashion. Yet, Medicare Advantage plans often put barriers to this management by adding additional steps to the pre-certification processes.

In addition to the amount of pre-certification work being done to little, if any, avail, given how few treatments or imaging actually get turned down by Medicare Advantage plans in the final analysis, the processes are
inefficient and decisions are often delayed for periods of time that are far from timely. Additionally, “fighting” for reversal of the initial decision is often required (often because the initial reviewer was simply not qualified to make the initial decision). This process rarely puts the patient first, given the delays and hurdles to treatment so many Medicare Advantage patients experience.

There is an emerging shortage of oncologists in the United States. Roughly, a third of oncologists are 64 years old or older and nearly two-thirds are older than fifty. As increasing documentation has crept into the health care space, fewer patients can be seen per day given the time constraints of the increasing documentation requirements. Given this looming shortage, focus on oncologists being at the bedside with patients, rather than at their computer terminal documenting unproven quality metrics, should be encouraged. This problem is compounded by the growth of Medicare recipients resulting from an aging population.

Recommendation:

- CMS should place guardrails on Medicare Advantage plans in terms of pre-certification. A concerted effort should be made to place the focus of this process on providing timely care for patients with cancer enrolled in Medicare Advantage plans. CMS should encourage such plans to look carefully at their processes, reminding those plans that their focus should be the care of their members in the least intrusive way, to patients and their providers of cancer care.

- Additionally, CMS should study the burdens of time and money that pre-certification processes in the Medicare Advantage space actually cost. Regulatory and administrative burdens clearly add cost. With high health care costs in a time of trying to improve the cost curve for health care in the United States, any processes that add time, hassle, or cost without clear, documented benefit in lowering health care costs, should be eliminated. Studying these hidden costs could lead to “exempt” status for the vast majority of providers who do the right thing day by day and unburden those providers so they can more effectively treat current patients, see more patients per day, and lower the costs of providing care at the provider level. Data to assess this approach is already being collected.

Inefficiencies of Electronic Health Records (EHRs):

Oncology has been uniquely involved in the use of electronic health records since their early emergence over 20 years ago. The documentation needs of patient records, the complexity of ordering of cancer therapies, and the need for safeguards in ordering and prescribing such complex and potentially dangerous antineoplastic therapies led to early adoption of EHRs by the oncology provider community. That said, there has yet to be a perfect EHR come to market.

As a whole, EHRs were designed as billing tools to ensure compliance with the myriad of documentation requirements, but not to necessarily enhance patient care. Most of these programs are revisions of old software from a computer era gone by. They are not transferable in terms of data exchange, are cumbersome to use, have led to resource utilization and significant expense on the part of providers, and create documents that make it hard to extract the essence of what should be recorded. The medical record has been perverted into a compliance and billing tool rather than the record and story of a patient’s journey.

However, there are clear benefits to electronic record keeping. Most oncology specific EHRs provide ordering and dose checking capabilities that add safety to procuring and giving antineoplastic therapies. This has been a monumental improvement. The ready access to records through computer technologies has clearly improved
the ability to view records from within and outside the office setting. Quality measures can be included within
the records and data to follow compliance with these measures can be extracted and analyzed.

That said, these cumbersome programs are not easy to use. It has been coined that EHRs are “click rich”
software and this certainly describes most currently available systems. They are time consuming and have
added significantly to the time spent in each patient encounter. These systems are expensive. Much of what is
recorded is to meet regulatory targets that have little impact on the patient’s journey. There is almost no
interchangeability of information between these systems so that, as an example, data from an office EHR
cannot populate a hospital EHR, more often than not. This leads to “double” and often inaccurate
documentation and often leads to excess costs of reduplication of testing along a patient’s journey. The tedious
nature of using such systems is a major contributor to physician burnout, something documented to be on the
rise.

Recommendations:

- CMS should be mindful of the shortcomings of electronic health records as they exist in the United
  States today. When policy decisions are made regarding documentation of quality metrics, or of
documentation requirements for patient encounters, researching the capabilities of current systems in
terms of ease of documenting, such information should be included in the development of such policy
decisions. Documentation requirements for all aspects of using electronic health records should be
made for betterment of patient care and should be focused on documentation that promotes and does
not detract from this goal. Policy in regard to documentation should not be made in a vacuum of not
understanding the capabilities of current systems.

- CMS should continue to encourage innovation toward interoperability of information exchange. The
time spent in redocumentation from system to system in a patient’s journey and the risks of errors that
come from disparity in software platforms, should be something paramount in priority. The waste of
reduplication in record keeping, laboratory testing, specialty referrals, imaging and medication
prescribing should make this a priority for lowering health care costs in the United States.

Documentation Requirements and Problems Within the CMMI OCM Model:

The Center for Medicare & Medicaid Innovation (CMMI) Oncology Care Model (OCM) has been
transformative in many ways. Quality cancer care is more defined than ever. This includes assuring specific
procedures have been followed and patients receive complete, appropriate, and timely information regarding
their care. The OCM has been transformative in another way. It has prompted the evolution of other reform
models.

These other models have observed the inefficiencies, complexities, and administrative burdens that are
inherent to the OCM. We count 20 current models in cancer care. These models are more transparent and
require much less administrative overhead when compared to the OCM. Some examples that illustrate the
administrative challenges within the OCM model include:

- The OCM finances the transformation efforts by paying $160 per month, per Medicare patient in active
cancer care. Many supporters of the OCM have suggested lowering this monthly amount. However,
the significant administrative and manual effort required to manage the model requires this degree of
financial assistance.
The OCM spawned many IT consulting firms to assist OCM participants. Some of these organizations include Caris, Archway, Tuple Health, and Flatiron, to name a few. These organizations have been very helpful in reviewing CMMI reports for participants, but they have also added a substantial layer of expense to the care team. They are best known for their ability to organize mounds of CMMI data to make the information useful to their client practices. Their intervention is required due to the manner and format of information that is released by the CMMI OCM team. This is expensive, cumbersome, and administratively burdensome. Examples include:

1. The reports are not separated by physician. This prevents the practice leadership from addressing behaviors that are not aligned with the OCM goals.
2. There are several tiers required to reconcile Medicare patients that are enrolled in the OCM. This prolonged process, which extends a year, is very labor intensive.
3. Reporting is not exception based. This requires careful review to determine which cases are beyond cost thresholds or when measure criteria are not met.

COA hosts a peer-to-peer support network for 80% of the OCM participants. This includes ongoing communications, face-to-face workshops, and monthly group discussions. Through three years of analyzing this model, COA is yet to identify any OCM participant that can declare specifically why they are doing well, or not doing well, in this model. The complexity and operational requirements within the model are not leading care teams to identifying and addressing specific areas where they can improve. The administrative burden is a distraction to understanding how to improve quality and value in cancer care – one of COA’s missions.

A more recent example of an inefficient system is the recent recommendation, from CMMI, for OCM teams to utilize the Medicare Blue Button tool to assist with the management and coordination of their patients. Although this electronic tool is patient friendly and organizes the Medicare patient’s record electronically, it is impractical for the cancer care team to utilize this tool to track, coordinate, and manage the patient’s care. The provider team would be required to educate each patient on the proper use and secure each patient’s waiver to access this data and the care support team would be required to submit an inquiry on each patient – individually and on a daily basis. All of this would be needed to track the patient. This would add layers of administrative effort and expense to the cancer care teams and their effort to manage their patients.

**Recommendation:**

- COA is a strong proponent for reform in cancer care. In the recent Physician Technical Advisory Committee (PTAC) application submitted by COA, OCM 2.0 reflects the vision and goal for demonstrating higher quality and value in cancer care. Through OCM 2.0, we strive to streamline a range of operational, quality measurement, and reporting processes with the goal of improving quality while also focusing on patient-centered care.

- The common denominator for “successful” and growing models is collaboration and communication. “Successful” should be a joint decision between the host of the model and the participants to agree upon the desired goals and to work cooperatively to achieve these goals as efficiently as possible. In the words of several OCM participants, “Model success is directly related to the degree of collaboration that is invested in the model”. Said another way, the new model itself should be as efficient as the care delivery that is being promoted and rewarded.
Currently, the OCM is lacking the level of collaboration and cooperation that participants and payers following the model have expected. Meaningful progress will be more effective and faster when attention is focused on removing the administrative burdens while still focusing on sustainable reform and value. CMS and CMMI should focus attention on the administrative burdens incumbent in the current OCM model and in all subsequent CMMI projects. While a certain level of reporting is necessary to ensure care quality in these programs, providers have entered a new paradigm in which they must complete requirements that extend far beyond clinical care for patients. In the continued shift from volume to value, care delivery costs and administrative burdens should not be increased in an effort to lower the total cost of care. In our opinion, this will not promote value.

**Conclusion**

COA’s unwavering commitment and steadfast determination to continually improve our cancer care delivery system is driven by a mission to ensure that patients with cancer continue to have access to the highest quality, most affordable, and most accessible cancer care in the communities where they live and work. We furthermore strive to ensure this care is provided in the most efficient and patient centric manner.

COA appreciates CMS’ efforts to reduce administrative burdens that have detracted from the true mission of community oncology practices, the care of cancer patients. We hope to see the fruits of this endeavor and remain willing to participate in meaningful ways to help achieve the goal of putting patients and their care over paperwork and bureaucracy.

We welcome the opportunity to work closely with CMS on these issues and discuss them in greater detail with you. Please do not hesitate to reach out to us.

Sincerely,

Michael Diaz, MD  
President  

Ted Okon  
Executive Director