



Oncology Nursing Society

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September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted online via regulations.gov

Re: CMS-1715-P – Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

The Oncology Nursing Society (ONS) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the aforementioned proposed rule.

Review and Verification of Medical Record Documentation

CMS proposes to establish a general principle to allow the physician, the PA, or the advanced practice registered nurse (APRN) who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students, or other members of the medical team. **ONS supports this proposal because it would further clarify and support CMS' efforts to reduce practitioner documentation burden while still ensuring that medical records include the information needed to demonstrate medical necessity and accurately document clinical findings, treatments, and ongoing care planning, as applicable.** The proposal also recognizes the important role of APRNs in this activity, which ONS appreciates.

Care Management Services

Care Management Services. CMS proposes several changes and/or solicits comments related to care management services, including: 1) revising its billing requirements and increasing payment for TCM services to increase utilization, 2) establishing a set of Medicare-developed HCPCS G codes for certain CCM services whereby clinicians can bill for CCM services incrementally to reflect additional time and resources required (in lieu of existing CPT CCM codes for clinical staff time), as well as adjusting billing

requirements related to typical care plan elements, and 3) establishing separate coding and payment for Principal Care Management (PCM) services, which describe care management services for one serious chronic condition.

We appreciate CMS' continued recognition of the value of care management services in the Medicare population. ***We generally support these proposals, but urge CMS to work with nurses to develop educational materials that will ensure correct use of these codes, particularly in light of the potential overlap in these services, the newly revised E/M services, and the complexity add-on code. We ask CMS to include specific scenarios that clarify the use of these new codes by APRNs.***

Comment Solicitation on Consent for Communication Technology-Based Services

CMS seeks comment on whether a single advance beneficiary consent could be obtained for a number of communication technology-based services. During the consent process, the practitioner would make sure the beneficiary is aware that utilization of these services will result in a cost sharing obligation. CMS seeks comment on the appropriate interval of time or number of services for which consent could be obtained, and on the potential program integrity concerns associated with allowing advance consent and how best to minimize those concerns. ***ONS supports a single advance beneficiary consent. Practitioners should be allowed to seek advance beneficiary consent for any combination of current communication technology-based services for no less than one year from the date the advance beneficiary consent is obtained.*** ONS does not believe that additional program integrity efforts are necessary to support such a policy, given that CMS' current audit programs should identify any unusual billing practices associated with these services.

Comment Solicitation on Opportunities for Bundled Payments under the PFS

CMS seeks comment on "opportunities to expand the concept of bundling to recognize efficiencies among physicians' services paid under the physician fee schedule (PFS) and better align Medicare payment policies" to improve individual health care, improve the health care of communities, and lower costs. ONS is concerned about the impact of efforts to expand bundled payments for cancer care and treatment under the PFS, given the challenges associated with current bundled payment programs, including the lack of transparency in existing programs and other alternative payment and delivery models. ***ONS recommends that CMS evaluate current bundled payment programs to certify that quality is accurately measured and maintained, and cost-savings are truly being produced, before expanding bundled payment programs under the PFS.***

Payment for Evaluation and Management (E/M) Visits

CMS proposes to rescind its finalized policy for CY 2021 to collapse the payment rates for Levels 2-4, as well as rescind the new prolonged services code. In its place, CMS proposes to adopt the recommendations of AMA CPT and RUC to restructure and revalue the codes. CMS also adopted a new time-based prolonged services code as put forth by CPT for use with Level 5 visits. These policies are all proposed to go into effect January 1, 2021.

We generally support these proposals, and urge CMS to finalize them. As noted above, we look to CMS to provide education and clarify the use of these codes considering the overlap in other care management services.

Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

Under current regulations, CMS may revoke a physician's or other eligible professional's Medicare enrollment if he or she has a pattern or practice of prescribing Part D drugs that: (1) is abusive, and/or

represents a threat to the health and safety of Medicare beneficiaries; or (2) fails to meet Medicare requirements. CMS proposes to revise these regulations to include Part B drugs, noting that this proposal would affect prescriptions of any Part B or D drugs, not merely those prescriptions given to beneficiaries using opioid treatment programs (OTPs).

ONS agrees that administrative actions by CMS to revoke the enrollments of practitioners who have engaged in a variety of improper prescribing practices have helped to shield beneficiaries and the Medicare program at large from potential harm. This proposal, however, fails to balance concerns regarding improper prescribing and patient harm against the need to ensure access to care for patients. The proposal is duplicative of current safety mechanisms and would result in undue ambiguity and burden for practitioners. Furthermore, what may be considered inappropriate or excessive prescribing for the general population could be clinically appropriate when taking a patient's individual circumstances into consideration, such as in the case of pain management and palliative care. Many "off-label" uses are both clinically appropriate and represent the standard of care.

CMS proposes to add a new revocation reason and a new denial reason to regulation text to permit CMS to revoke or deny, as applicable, a physician's or other eligible professional's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

ONS considers this proposal an overreach by the agency, given that the factors CMS would consider in determining whether a revocation or denial on this ground is appropriate are not necessarily indicative of patient harm. The proposed rule does not outline clear standards for how CMS will determine whether there are sufficient grounds to revoke or deny enrollment based on patient harm, and the inclusion of "any other information that CMS deems relevant to its determination" as a factor in determining a revocation or denial would provide the agency with overly broad discretion in making enrollment decisions. ***It is for these reasons that ONS opposes CMS' enrollment revocation and denial proposals.***

Deferring to State Scope of Practice Requirements: Hospice

CMS proposes to revise its regulations to permit a hospice to accept drug orders from a physician, NP, or PA. CMS also seeks to fully understand the current and future role of NPPs in hospice care and the hospice CoPs, and requests public comment on several questions.

- *What is the role of a NPP in delivering safe and effective hospice care to patients? What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?*

The Clinical Practice Guidelines for Quality Palliative Care, 4th edition, updated and released in 2018 clearly defines recommendations for interdisciplinary teams to include: "a team of physicians, advanced practice registered nurses, physician assistants, nurses, social workers, chaplains, and others based on need." Advanced practice registered nurses (APRNs) (notably, nurse practitioners [NPs]) provide complex symptom management including ordering and interpreting tests, making referrals and prescribing medications, having goals of care conversations including DNR, order transitions in care to hospice, and provide support for patients and their families directly and through referrals. As integral members of the palliative

care teams on which they work, NPs may serve as clinicians and educators, patient care advocates, and also in leadership roles. They should be allowed to provide the same level of support and care on hospice teams. NPs should be allowed to provide ongoing management and patient care including palliative and supportive care and transitions to hospice care.

- *Nursing services are a required core service within the Hospice benefit, as provided in section 1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?*

In current clinical practice, NPs, and physician assistants (PAs) have similar position descriptions and responsibilities. However, PAs are required to have physician supervision. NPs have varying levels of independence of practice (with or without physician supervision) based on state laws. Twenty-three states provide NPs with full and independent scope of practice.

- *In light of diverse existing state supervision requirements, how should NPP/APP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?*

For continuity of care and administrative simplification, Medicare policy should enable non-physician practitioners to continue to deliver care to Medicare patients to the full scope of practice as determined by state boards of practice in each state. While the scope of practice varies by state from full independence without a supervising physician (23 states for NPs) to varying levels of supervision including a necessitated supervising physician for physician assistants, CMS should allow parity for all non-physician practitioners providing the same care as a physician. This will help improve equity and reduce disparities in care and improve the delivery of quality care. It also permits flexibility to accommodate changing models of hospice care which may include telemedicine including across state lines, home-based palliative to hospice models of care, and changes needed to meet the needs for access to hospice and palliative care in rural and remote settings.

- *What requirements and time frames currently exist at the state level for physician co-signatures of NPP? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?*

If under state law, non-physician practitioners do not require physician co-signature for any other specialty, signatures should not be mandated for hospice practice. Transitions to hospice benefit should be under the license of APPs (NPs and PAs) in states that have independence of practice and do not require a supervising physician.

- *What are the essential personnel requirements for PAs and other NPPs?*

There should be a thoughtful and a flexible process so as not to inadvertently limit the hospice care workforce. All non-physician providers should be part of a discussion on all non-physician provider competency standards and expectations.

CY 2020 Updates to the Quality Payment Program

Merit-based Incentive Payment System (MIPS) Value Pathways (MVP) Framework

CMS proposes to apply a new MIPS Value Pathways (MVP) framework to future proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year. According to the proposed rule, the MVP framework would create a more cohesive participation experience by connecting measures and activities from across the four MIPS performance categories that are relevant to a specialty or medical condition, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients.

The four guiding principles CMS would use to define MVPs are:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVPs should include measures that encourage performance improvements in high priority areas.
4. MVPs should reduce barriers to alternative payment model (APM) participation by including measures that are part of APMs where feasible and by linking cost and quality measurement.

ONS thanks and commends CMS for its focus on creating a more cohesive and simplified MIPS participation experience. Increasing data and feedback to clinicians in an effort to reduce reporting burden, and facilitate movement towards APMs is of high priority. Further, we believe the MVP guiding principles (above) are relevant to the goals of the QPP; further definition is not necessary.

Nevertheless, ONS is concerned that the proposed MVP framework does not meaningfully address the most significant underlying problems with MIPS. As currently envisioned, the framework does not truly unify the MIPS performance categories of *Quality, Improvement Activities, Promoting Interoperability (formerly Advancing Care Information), and Cost*. Instead, it connects each category under a common theme while maintaining distinct sets of measures, activities, reporting and scoring rules, ultimately resulting in a single incentive payment. ONS believes that it is crucial for the framework to provide cross-category credit in order to eliminate duplicative reporting and enable clinicians to spend their time tracking their performance rather than tracking compliance, in order to provide the best care possible for all oncology patients including those participating in clinical trials. ONS believes that the current statute grants CMS the flexibility necessary to adopt a more consistent, less complex policy that incentivizes innovative demonstrations of high-quality, high-value care.

We also believe a “Call for MVPs” as described in the proposed rule would likely produce a more robust and meaningful outcomes measurement across quality as using the specialty sets with revisions would seem inadequate. The current specialty measure sets are long standing process measures, that may be useful for internal performance improvement but appear to be of limited value in the goal of addressing priority outcomes. ***ONS strongly agrees that outlier analysis and other types of actionable data as performance feedback is vitally important to eligible clinicians and strongly believes, based on our experience as a QCDR vendor, that this is a very important benefit of the QCDR.*** Many platforms can provide clinicians with near real-time performance data in the form of outlier reports and actionable performance data by measure and provider.

In addition, **ONS supports the requirement that measures be fully specified prior to inclusion in the QPP.** We further espouse our experience that the best method of testing a measure is a fit-for-purpose approach after a measure has been fully deployed in the QCDR and utilizing the data from implementation for testing as opposed to requirements for specialized testing. As a QCDR vendor and measure developer, ONS has utilized both methods of testing and based on this experience, promotes measure testing through provisional implementation in real-world conditions as a practical approach. While the measures in ONS' QCDR are eQMs, the reality is that many of our sites/potential subscribers are asking for registry/manual measures. After spending 2018 and 2019 in both measure development and measure maintenance activities, we continue to find that eQMs requiring patient level eHR clinical assessment, PRO data or diagnostic data are not consistently feasible – even in large academic medical centers. For this reason, **we suggest that CMS consider maintaining similar measures with different collection types – even in the face of creating and maintain separate benchmarking at this time.**

Despite the effort to reduce clinician burden through MVPs, as a QCDR vendor, we have concerns that the magnitude of this change will create confusion for clinicians and vendors given the aggressive timeline proposed. **We encourage CMS to consider allowing more development time, and perhaps some pilot testing prior to implementation of the MVPs.**

Finally, to the extent MVPs address cancer care and treatment, **we urge CMS to ensure oncology nurses are able to meaningfully participate in the MVP development process. We further encourage CMS to ensure its MVPs consider the continuum of care for all patients, particularly those with a cancer diagnosis.**

Qualified Clinical Data Registry (QCDR) Provisions

CMS requests comments on policies for how QCDR measures would be used in MVPs – asking whether they should be integrated along with MIPS measures, or be limited to specific MVPs consisting only of QCDR measures. CMS also questions how the agency should continue to encourage clinicians to use QCDRs under MVPs. ONS is of the belief that QCDR measures should be integrated along with MIPS measures in MVPs. However, because the proposed rule does not provide enough detail to allow stakeholders to respond to these questions in an informed manner, **ONS recommends that CMS publish a separate request for information or notice of proposed rulemaking to address these issues.**

CMS proposes to require that QCDRs provide performance feedback to participants at least four times a year and provide specific feedback on how they compare to others who have submitted data on a given measure within the QCDR. **ONS notes that the frequency of feedback reports that would be required by this proposal does not seem necessary for QCDRs that do not have adequate data from their clinicians and groups.**

CMS proposes to amend current regulations to state that the agency may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. **ONS believes that the owners of QCDR measures should be responsible for the monitoring and controlling of licensees and users.**

CMS proposes that beginning with the 2021 performance period and future years that QCDRs must identify a linkage between their QCDR measures to the following, at the time of self-nomination: (a) Cost measure; (b) Improvement Activity; or (c) CMS developed MVPs. **ONS requests additional**

clarification regarding this proposal; specifically, are QCDRs required to identify a linkage between their measures and all three items outlined? Also, how will QCDRs be required to “identify a linkage?”

Beginning with the 2021 performance period, CMS proposes that all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. Given the time and expense required for full National Quality Forum (NQF) testing, **ONS opposes this proposal due to the burden that it would impose on QCDRs.**

CMS proposes to implement, beginning with the 2021 performance period, two-year QCDR measure approvals, at the discretion of the agency, for QCDR measures that attain approval status by meeting the QCDR measure considerations and requirements. **ONS supports this proposal.**

We appreciate the opportunity to comment on this proposed rule. If you have any questions about our comments, please contact Valerie A. Adelson, MHA, BSN, RN, Director, Government Affairs at vadelson@ons.org.

Sincerely,

The Oncology Nursing Society

About ONS

The Oncology Nursing Society (ONS) is a professional organization of over 39,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.