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August 21, 2017

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-5522-P, Medicare Program, CY 2018 Updates to the Quality Payment Program, 42 CFR Part 414

Submitted electronically via Regulations.gov

Dear Ms. Verma,

The Oncology Nursing Society (ONS) is writing to share sentiments on key proposals outlined in the CY 2018 Updates to the Quality Payment Program (QPP) as they relate to ongoing implementation of the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) and the impact on cancer care delivery and treatment.

MIPS Payment Adjustments

ONS strongly opposes CMS' policy to include Part B drugs in the calculation of MIPS payment adjustments, which may have a detrimental effect on the provision of chemotherapy, particularly in small and rural practices that already struggle to purchase chemotherapy medications for their Medicare patients at Average Sales Price (ASP) +6%, not counting the reductions due to sequestration, which further reduce this rate closer to ASP +4.3%, if they fail to meet MIPS program requirements. The impact of a negative MIPS adjustment could permanently close the doors of small and rural oncology practices, limiting access to medically necessary cancer care to the most vulnerable Medicare beneficiaries. For an oncology practice that performs well, a substantial proportion of the incentive payment would be driven by the cost of chemotherapy medications, which is in contrast to efforts aimed at addressing high drug prices, and directly conflicts with the very intent of the Medicare Access and CHIP Reauthorization Act (MACRA) to incentivize the value of care delivery over the volume of services rendered.

Under CMS' recently sunset quality reporting programs, including the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM) and Electronic Health Record (EHR) Incentive Program, Part B drugs were excluded from upward and downward adjustments. However, in this proposed rule, CMS seems to be "clarifying" that Part B drugs are subject to such adjustments under the MIPS program, rather than providing a clear proposal for stakeholders to consider and provide comment on. If CMS finalizes this policy, it would violate the Administrative Procedures Act (APA), because stakeholders were not provided a clear proposal on which to consider and provide comment, thus the "logical outgrowth" test would not have been met.

Moreover, CMS' interpretation of the statute that led it to conclude that Part B drugs are subject to the MIPS payment adjustment, should be reconsidered. MIPS was specifically designed to consolidate and streamline payment adjustments under CMS' predecessor quality payment programs – not expand them. The MIPS payment adjustment provisions are included in Section 1848 of the Social Security Act (the Act), which is entitled "payment for physician services" and pertains to payment under the physician fee schedule (PFS). If Congress meant for MIPS adjustments to include Part B drugs, it would have made that clear in the law. Also, under the Advanced APM track of the QPP, Part B drugs are not included in the incentive payment. Congress would not have included Part B drugs in the payment adjustment under one track of the QPP and not the other.

Oncology nurses, especially those working in community-based oncology practices and in rural and underserved areas, should not be impeded from administering and monitoring the medically necessary anti-cancer drugs that their patients need. Cancer is complex to treat, and some patients may need certain drugs that are more expensive than others to ensure desired outcomes and adherence

to clinical pathways. Unfortunately, if these oncology practices cannot acquire medications at a price equal or less than the current ASP rate, patients will suffer and will likely seek alternative care in more expensive hospital settings, driving up Medicare costs. The current ASP payment rate (ASP +6%) helps cover unreimbursed costs that a practice incurs, including oncology nursing services. Without an oncology nurse in the practice to provide required cancer therapies patient education (which can prevent unwanted admissions to the ER), and safely administer the cancer therapies, practices could not exist.

CMS must reconsider its policy and exclude Part B drugs from MIPS eligibility determinations and payment adjustments. MIPS payment adjustments should only apply to covered PFS services.

MIPS Performance Category Measures/Activities

Advancing Care Information (ACI) Performance Category

CMS seeks comment on how the ACI performance category could be applied to Nurse Practitioners (NPs), Physician Assistants (PAs), Clinical Nurse Specialists (CNSs), and Certified Registered Nurse Anesthetists (CRNAs) in future years of MIPS, and the types of measures that would be applicable and available to these types of MIPS-eligible clinicians. In addition, through the Call for Measures Process, CMS seeks new measures that may be more broadly applicable to these additional types of MIPS-eligible clinicians in future program years.

Oncology nurses are active users of electronic health records (EHRs) and qualified clinical data registries (QCDRs) in the provision of cancer care and treatment and for quality improvement. Measures that will appropriately and accurately account for how oncology nurses apply health information technologies in oncology practice are key to assisting in their robust participation in MIPS, and specifically, the ACI performance category. We urge CMS to establish a technical expert panel (TEP) that would specifically look to develop ACI measures that capture the contributions of nurses, particularly in cancer care. ONS would welcome the opportunity to submit nominations to such an effort given the expertise within our staff and membership on the use and application of health information technologies in cancer care delivery and treatment. As you know, ONS launched a QCDR that is currently recognized by the agency for use in MIPS.

APM Incentive

PFPM Criteria

ONS continues to believe that nursing and nursing services will be pivotal in care delivery improvements that promote better care coordination, protect patient safety, and encourage patient engagement, which are key to the development of alternative payment models (APMs), including Physician-Focused Payment Models (PFPMs). The Physician-Focused Payment Model Technical Advisory Committee (PTAC) plays an important role in assessing PFPM proposals and has the authority to encourage the inclusion and underscore the value of nursing in meeting the Secretary's goals. Unfortunately, PTAC does not consider whether the role of nursing has been factored into the PFPM or not, even for models directed at cancer care where oncology nurses are known to play a critical role. **The role of nurses should be a criterion for evaluating PFPM proposals, and PTAC should be closely assessing whether nursing has been incorporated in PFPM proposals**, particularly in the area of care delivery improvements. We urge CMS to modify the PFPM criteria to incorporate the role of nursing.

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ONS appreciates the opportunity to comment on this important issue of quality measurement. ONS looks forward to continuing dialogue on these important issues. If you have any questions about our comments, please contact Donna (Dede) Sweeney, ONS Director of Government Affairs, at dsweeney@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.