



American Society of Transplant Surgeons

Saving and improving lives with transplantation.

August 21, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; CY 2018 Updates to the Quality Payment Program; 42 CFR Part 414 [CMS-5522-P] RIN 0938-AT13

Dear Administrator Verma:

On behalf of the American Society of Transplant Surgeons, I am pleased to have this opportunity to comment on the 2018 MACRA Proposed Rule (the "Proposed Rule"). ASTS is a medical specialty society representing approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

Preliminarily, please note that a number of the comments below relate to the need to establish appropriate measures and incentives for the provision of team-based care. Transplantation is likely one of the best examples of team-based medicine: Successful transplant programs integrate the services provided by a wide range of medical, surgical, other clinical and non-clinical personnel, including transplant physicians, transplant surgeons, social workers, pharmacists, transplant coordinators, specially trained nurses, and others. There are other areas of medicine (cancer, geriatrics, trauma/ICU/rehab) where complexity and intensity of care require that one embrace a team approach, and we urge CMS to consider the comments below in this context.

Our comments on the Proposed Rule focus on the following issues:

AAPMs: Quality Measures under the CEC Demonstration Program

Merit-Based Incentive Payment System (MIPS)

- Proposed implementation of virtual group reporting
- Proposed implementation of quality and cost reporting for Facility-Based Physicians
- Proposed provisions related to quality component of MIPS
- Proposed provisions related to Qualified Clinical Data Registries (QCDRs)

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I. AAPMs: Quality Measures under the CEC Demonstration Program

Under the Proposed Rule, End Stage Renal Disease (ESRD) Comprehensive Care Organizations (ESCOs) that participate in the Innovation Center Comprehensive ESRD Care (CEC) initiative in 2018 would continue to qualify as AAPMs. ESCOs are essentially ESRD-specific ACOs; however, as we understand it, if a beneficiary assigned to an ESCO receives a transplant, the ESCO is no longer eligible for shared savings. Thus, ESCOs have an incentive to refer for evaluation only those ESCO-aligned Medicare beneficiaries for whom they do not believe savings are achievable (i.e., sicker patients who consume relatively more Part A and Part B medical services).

The potential impact of the CEC initiative on referrals for transplant evaluation is critically important. The average kidney transplant recipient lives more than twice as long as he/she would if remaining on dialysis (USRDS data) and enjoys markedly improved quality of life and longevity: Life expectancy after starting dialysis is 5.7 years and after kidney transplantation is 15.8 years. Thus, to the extent that the CEC model disincentivizes the referral of appropriate ESCO-aligned Medicare beneficiaries for transplant evaluation on a timely basis, this model has the potential to significantly and adversely impact the life expectancy and quality of life of these Medicare patients.

In addition, since transplantation is by far the most cost-effective treatment option for patients with ESRD, to the extent that the CEC initiative disincentivizes transplantation, it has the potential to increase, rather than decrease, ESRD costs of care. Kidney transplantation is associated with a cost savings of as much as \$200,000 per transplant over the first 5 years after transplantation. (Examination of Medicare spending reveals the breakeven point for transplantation vs. dialysis is 2.3 years for patients who undergo living donor transplantation and 3.6 years for recipients of deceased donor transplantation.)

Recommendation: We strongly urge CMS to refrain from continuing to authorize ESCOs to qualify as AAPMs unless and until strong safeguards are designed and appropriate monitoring is in place to ensure that LDO ESCOs refer ESRD patients for transplant evaluation as clinically indicated and without regard to financial considerations.

II. MIPS

A. Virtual Groups

We recognize the administrative difficulties involved in the implementation of virtual group reporting under MIPS and appreciate CMS's efforts to overcome these difficulties in order to provide a reporting mechanism for virtual groups. Under the Proposed Rule, a virtual group would be defined as:

[A] combination of two or more TINs composed of a solo practitioner (a MIPS eligible clinician (as defined at §414.1305) who bills under a TIN with no other NPIs billing under such TIN) or a group (as defined at §414.1305) with 10 or fewer eligible clinicians under the TIN that elects to form a virtual group with at least one other such solo practitioner or group for a performance period for a year.

While we understand the need to establish a definition of virtual group that accommodates the needs of solo practitioners and small groups, we believe that, in light of the proposed decrease in the low volume threshold, it is likely that many of the physicians and other clinicians that might otherwise benefit from this definition are likely to be exempt from MIPS reporting. In addition, many smaller groups likely will not have any incentive to pursue this route to MIPS reporting, since combining with another small group may jeopardize their qualification for

various exemptions and exceptions available to small groups (e.g., quality component bonus points and the new proposed ACI hardship exception for small groups.).

At the same time, it appears that the definition would preclude subgroups of highly specialized physicians in larger group practices from qualifying as a “virtual group” and being measured on their own quality and cost performance. For example, transplant surgeons may provide professional services under the TINs assigned to faculty practice plans and multi-specialty groups; however, the quality and cost of transplantation is most accurately measured based on the performance of a discrete transplant team. The proposed definition of “virtual group” would not accommodate quality reporting by the transplant team.

Recommendation: We recommend that CMS consider the feasibility of establishing a mechanism for virtual group reporting for highly specialized physicians and other clinicians who constitute a subgroup of those reporting under a single TIN.

B. Quality and Cost Reporting for Facility-Based Physicians

1. Facility-Based Clinician and Facility-Based Practice Definitions

We appreciate CMS’ efforts to implement provisions of MACRA that authorize the use of quality and cost measures used for other providers for MIPS reporting purposes. Under the Proposed Rule, facility-based physicians would have the opportunity to opt to have their quality and cost component MIPS scores based on the hospital value based modifier scores of the hospital in which they provide a majority of inpatient services.

For this purpose, the Proposed Rule defines a “facility based” eligible clinician as one who furnishes 75 percent or more of his or her covered professional services in inpatient and emergency room sites of service. Under this definition, we would anticipate that many transplant surgeons will qualify as facility based under the Proposed Rule, if they report as individuals.

However, it is not entirely clear whether transplant surgeons will qualify for facility-based measurement if they report as part of a physician group. Under the Proposed Rule:

a facility-based group is a group in which 75 percent or more of the MIPS eligible clinician NPIs billing under the group’s TIN are eligible for facility-based measurement as individuals.

Under this definition, while group practices primarily composed of surgeons may qualify for reporting as facility-based groups, many faculty practice plans and multi-specialty groups will not be qualified to adopt facility-based measurement.

The Proposed Rule solicits comments on whether an alternative definition of facility-based group should be adopted under which a facility-based group would be a group where the TIN overall furnishes 75 percent or more of its covered professional services in inpatient and emergency room sites of service. While it is possible that this would facilitate facility-based measurement of additional groups, we believe it is still unlikely that multi-specialty groups and faculty practice plans will qualify.

Recommendation: We urge CMS to either lower the threshold of physicians/services required to be considered facility based in order for a physician group to qualify as facility based or establish a

mechanism for facility-based physicians who are part of a larger group to report separately, as a “virtual group” (as discussed above in the section of these comments addressing the virtual group definition).

2. Use of Hospital VBP Scores for MIPS Quality and Cost Reporting

Mandated by the ACA, the VBP program pays hospitals for their actual performance on quality and cost measures, rather than just the reporting of those measures and to this extent it is conceptually similar to MIPS. Also like MIPS, the hospital VBP program is budget-neutral: any hospital inpatient payment reductions implemented under the program must be distributed to other hospitals. For these reasons, we understand the rationale for CMS’ proposal to use the hospital VBP scores as the basis for quality and cost component measurement of facility-based physicians under MIPS.

If CMS finalizes its proposal to authorize the use of a hospital’s VBP score for scoring facility-based physicians under MIPS, we urge the agency to proceed expeditiously in establishing an appropriate adjustment for patient socioeconomic status under the hospital VBP program. We believe that the socioeconomic status of a hospital’s patient population has the potential to significantly impact its VBP score, and hence the MIPS scores of its facility-based physicians.

If the hospital VBP scores are used for the purposes of MIPS, we urge CMS to consider MIPS implications whenever changes in the hospital VBP program are under consideration, and to keep the hospital VBP measures as general as possible. For example, we note that CMS has proposed to weight condition-based measures (focused primarily on cardiac conditions) as 50% of a hospital’s efficiency/cost domain score, with Medicare Spending Per Beneficiary (MSPB) as the other 50%. Weighting condition-specific performance may or may not be appropriate in determining hospital scores; however, since many facility-based physicians (including transplant surgeons) have no control whatsoever over hospital efficiency or cost for admissions outside of their specialty areas, weighting condition-specific performance so heavily clearly makes hospital VBP scores somewhat less appropriate for scoring facility-based physicians under MIPS. In general, the more general the VBP hospital measures, the more likely they are to be appropriate for MIPS reporting purposes.

Finally, if CMS does believe that it is appropriate to continue to use conditions-specific hospital measures in assessing the performance of provider-based physicians under MIPS, we urge the agency to give transplant surgeons the option to be measured based on transplant outcomes, as determined by transplant center compliance with applicable Medicare Conditions of Participation.

Recommendation: We urge CMS to adopt a provision that enables a transplant surgeon and other members of the transplant team to elect to use either their institution’s performance rates under the outcomes requirements set forth at 42 CFR §482.80(c) and §482.82(c) as a proxy for the transplant surgeon or other MIPS eligible clinician’s quality score such as the SRTR (or CMS) reported outcomes .

C. MIPS Quality Component

It appears that the quality component of MIPS will be the most critical for most of our members in 2018, especially since CMS is proposing to assign a zero weight to the cost component of the program in 2018 and since the Advancing Care Information (ACI) component of the program will be inapplicable to transplant surgeons qualifying as “hospital-based” physicians.

As indicated in prior comments, transplantation is among the most heavily regulated of health care services provided in the United States. Not only are Transplant Centers required to comply with comprehensive Medicare conditions of participation in addition to (and operated in conjunction with) hospital conditions of participation, but these centers are also subject to comprehensive regulation by the Organ Procurement and Transplantation Network (OPTN), which is funded through the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. As the result of both sets of regulations, transplant surgeons and other clinicians involved in the transplantation process are required to meet numerous quality requirements that are not applicable to other physicians.

In light of the extraordinary quality requirements already imposed on transplant surgeons and other members of the transplant team, we believe that clinicians whose primary practices focus on transplantation either should be exempted from MIPS quality requirements or should be given credit in the MIPS quality component for the activities and reporting that are already required through Medicare Transplant Center certification requirements, OPTN requirements and SRTR reporting requirements. For many transplant surgeons, it is not possible to identify quality measures among those proposed, and the measures that are available are only generally (or not at all) relevant to achieving high quality outcomes.

Specifically, our review of the proposed measures suggests that transplant surgeons may be in a position to report a number of general perioperative, medication reconciliation, and preventive care and screening measures, but these measures are too general as indicators of quality in transplantation and their utility to patients and providers pales in comparison with the utility of the SRTR outcomes measures which provide patients with actionable data on patient and organ survival. We believe that it may be useful to consider the addition of a number of transplant-specific outcomes measures to those reportable under the quality component of MIPS and that CMS approve these measures as a specialty measure set.¹

We also note that CAHPS, which is reportable as a quality measure under the Proposed Rule, is not currently useful for transplantation, and even the S-CAHPS (developed for use in the provision of surgical care) is of limited utility. This is primarily because, in the case of transplant surgery, unlike many elective surgical procedures or other surgeon based practices, the patient may have had no prior interaction with the surgeon who ultimately performs the surgery. Furthermore, the long interval between evaluation and listing resulting from the waiting list, which is beyond the control of the surgeon, affects patient perceptions of doctor-patient communication and patients often are severely debilitated, frequently confused or encephalopathic, and in poor health (which is required to achieve sufficient priority to be transplanted). This certainly impacts patient perception and satisfaction. Moreover, a major aspect of provider/patient perioperative communication and quality of care focuses on immunosuppressive and other medications, which is not addressed by CAHPS or even S-CAHPS.

¹ For example, these might include:

- Number of adult (18 or over) [organ][patient/graft] survival at one month/SRTR Expected number of [organ][patient/functioning graft] survival at 1 month(adjusted for patient and donor characteristics)
- Number of adult (18 or over) [organ][patient/graft] survival after one year/SRTR Expected number of [organ][patient/functioning graft] survival at one year post transplant (adjusted for patient and donor characteristics)
- Number of adult (18 or over) [organ][patient/graft] survival after three years /SRTR Expected number of [organ][patient/functioning graft] survival at three years post transplant (adjusted for patient and donor characteristics)

Recommendation: We believe that a measure of patient experience of care (CAHPS or other than CAHPS) should be used under the CPIA component of MIPS, rather than as an element of the quality component of the program. Alternatively, we urge CMS to work closely with the transplant community and the American College of Surgeons to adopt a patient experience of care measure that is relevant to all surgeons, including transplant surgeons, and that adequately takes into account the team-based nature of transplantation and other complex surgery.

Finally, we note that the Proposed Rule would continue to determine physicians' quality scores based in part on population-based measures that were developed for use in other contexts. It is our understanding that hospital readmissions are indirectly taken into account in these population-based quality measures. While we appreciate and respect the need to reduce overall readmissions, transplantation is very different. Readmission is not only commonplace for patients receiving transplants due to their comorbidities and the magnitude of the procedure, it is more frequent than in other procedures or therapies and is often necessary to ensure that patients do not reject the transplanted organs. Organ rejection is not only a dangerous health condition but it is costly to the Medicare program and wasteful of the precious gift of life, the donated organ. Patients who return to the hospital do so not only related to complications of the transplant or their immunosuppressant medications, but also quite often for issues unrelated to the transplant. (For example, there is a substantial risk of infection in patients on immunosuppression, which requires a higher level of vigilance than patients not on these medications.) Thus, failure to readmit transplant patients is a patient safety issue. Also, readmission reflects the severity of illness of patients reaching transplant.

It is the transplant physician and team's role to strive to reduce readmissions; however, the reality is that readmission rates are—and, in the interests of patient safety and high-quality care, likely should be—disproportionately higher for transplantation than for many other inpatient procedures. In the context of MIPS, then, taking readmissions into account in quality scoring—or in any other context—effectively discriminates against transplant surgeons who report individually and groups that include transplant surgeons and other transplant clinicians.

Recommendation: We urge CMS to remove the population-based quality measures from consideration under the quality component of MIPS for members of the transplant team.

D. Proposed Provisions Related to QCDRs

ASTS has considered submitting an application for the SRTR to qualify as a QCDR; however, since many transplant surgeons are members of larger groups or organizations that may have established reporting mechanisms, it has been unclear to us whether or not the SRTR would be widely utilized to report quality measures under MIPS. Under the Proposed Rule, a physician or physician group would have the opportunity to report quality measures using more than one reporting mechanism. This provision has the potential to increase the use of QCDRs for quality reporting, which is consistent with Congressional intent and may open increased potential for SRTR as a QCDR.

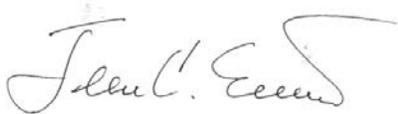
Recommendation: We urge CMS to adopt provisions of the Proposed Rule that would facilitate quality reporting through more than one reporting mechanism, since we believe that this change may encourage quality reporting through QCDRs.

Obtaining approval of SRTR as a QCDR is complicated both by the team-based nature of transplantation and by the numerous technical and other requirements that QCDRs are required to meet. At this time, SRTR data is reported to the public on a transplant center level, and ASTS strongly opposes any attribution of transplant outcomes to individual surgeons, physicians or other clinicians. On the other hand, MIPS scorecards require that quality measurement take place at the individual (NPI/TIN) or physician group (NPI/TIN) basis, and not all members of a transplant team may be in the same group.

Recommendation: In light of Congressional intent to encourage the use of QCDRs, CMS should not only simplify the process for re-approval of QCDRs, but should also consider substantially streamlining and simplifying the process for approval of new QCDRs, including revision or elimination of any requirement that, to be approved as a QCDR, the SRTR report quality performance on an individual level. For transplant, given the nature of the collective decision making for listing, organ acceptance, and post-transplant management, individual assignment is not reasonable nor informative, and outcomes should be reported only on a collective basis.

We appreciate the opportunity to submit these comments for your consideration. If you have any questions, please do not hesitate to contact Kim Gifford, ASTS' Executive Director, at kim.gifford@asts.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jean C. Emond". The signature is fluid and cursive, with a large, sweeping initial "J" and a long, horizontal flourish extending to the right.

Jean C. Emond
President
American Society of Transplant Surgeons