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Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW., Washington, DC 20201

CMS-3321-NC: Request for Information (RFI) Regarding Implementation of the Merit-based Incentive Payment System (MIPS), Promotion of Alternative Payment Models (APMs), and Incentive Payments for Participation in Eligible Alternative Payment Models (EAPMS)

Dear Acting Administrator Slavitt:

On behalf of the American Society of Transplant Surgeons, I am pleased to have the opportunity to submit these comments on the RFI. 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.

Transplantation is unique in that it is highly dependent on heterogeneous organ quality and availability, as opposed to other surgical specialties which implant manufactured devices with known reliability. Donor organ quality is captured by the Scientific Registry of Transplant Recipients (SRTR), which is a data repository the scope of which is unique to transplantation.

These comments focus on:

- Ensuring that the quality component of MIPS is structured in a manner that is sufficiently flexible to enable the SRTR to be used for the quality scoring purposes;
- Ensuring that the clinical practice improvement activity (CPIA) component of MIPS is structured in a manner that is sufficiently flexible to enable the SRTR and transplant center accreditation to be used for CPIA scoring purposes;
- Ensuring that eligible alternative payment model requirements are structured in a manner that enables transplant surgeons at hospitals that participate in Accountable Care Organizations (ACOs) and Bundled Payment for Care Improvement (BPCI) programs to qualify as "qualifying APM participants" for the purposes of bonuses and MIPS exemptions.

SRTR: Background

Over the past year, ASTS has had a number of discussions with CMS about the possibility of gaining approval of the SRTR as a qualified clinical data registry (QCDR) for the purposes of the Physician Quality Reporting System (PQRS); however,

ASTS placed these discussions on hold in light of MACRA's repeal of PQRS in its current form. We believe that the time is now ripe to revisit the potential for SRTR to play a critical role in quality evaluation for transplant surgeons and other eligible professionals (EPS) under the Merit-based Incentive Program (MIPS) authorized by MACRA. In particular, we would like to re-institute consideration of SRTR as a QCDR for the purposes of MIPS quality measurement and CPIA MIPS metrics.

SRTR is a comprehensive national database of transplantation outcomes and other information. The SRTR operates under contract with the Health Resources and Services Administration, a sister agency to CMS within HHS. The SRTR transplant program reports include:

- Reliable transplant information for patients, families, and medical professionals;
- A complete list of U.S. transplant centers;
- Waiting time and organ availability data for each center; and
- Patient and organ survival statistics.

The SRTR provides detailed patient and organ survival and other outcome information for every transplant for each transplant center and each type of organ transplant (i.e., kidney, liver, heart, heart-lung, pancreas, intestine, kidney-pancreas). Each center's performance is risk adjusted and reported against applicable benchmarks. Actual performance is compared to "expected" performance on key measures, taking into account sophisticated (albeit as-yet-imperfect) risk adjustment methodologies.

This information, which is made public, is precisely the type of specific, accessible outcome information that patients and prospective patients want and need. And, in addition to contributing data for the program specific reports, transplant centers also report on more than 256 data elements required by the National Organ Transplant Act, contributing to a rich and unique database on virtually every aspect of transplantation in the United States. The SRTR is also a powerful quality improvement tool for providers, shown to steadily improve care. Its research capabilities are routinely harnessed by transplant teams to drill down to patient subgroup outcomes, analyze risk factors, and better understand performance at the subgroup level, center level and multicenter level.

SRTR: Approval of the Use of the SRTR as a QCDR Is Consistent with MACRA

MACRA directs CMS to use QCDRs to the extent practicable under MIPS ("USE OF REGISTRIES.—Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection.") A number of provisions suggest that approval of the SRTR as a QCDR is consistent with the purposes underlying MACRA. For example, MACRA:

- Specifically directs CMS to emphasize outcomes measures in formulating the quality component of MIPS ("In applying [the quality component of MIPS], the Secretary shall, as feasible, emphasize the application of outcome measures.").

  The SRTR is among the few ongoing and well-established registries that focus on patient outcomes.

- Authorizes CMS to use hospital measures in determining physician scores under the quality component of MIPS. ["APPLICATION OF ADDITIONAL SYSTEM MEASURES.—The Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the performance categories described in [the quality and value components of MIPS]."]

  SRTR reports performance at the transplant center level ("Transplant Center Specific Reports").

- Specifically authorizes the use of global and population-based measures under the quality component of MIPS. ["(iii) GLOBAL AND POPULATION-BASED MEASURES.—The Secretary may use global measures, such as global outcome measures, and population-based measures for purposes of the [quality] performance category for MIPS."]

  SRTR is among the only ongoing and well-established registries that use patient outcome and population-based measures, such as wait list data.

- MACRA specifies that participation in a QCDR qualifies as a CPIA and defines a CPIA as an activity that stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

  UNOS, which currently holds the HRSA contract as the Organ Procurement and Transplantation Network, utilizes the SRTR to enforce practice improvement, through the activities of the UNOS Membership and Professional Standards Committee (MPSC). In addition, the Medicare program utilizes SRTR data as a critical element in determining transplant center compliance with the Medicare conditions of coverage for transplant centers, and transplant centers that fail to meet SRTR outcomes parameters are required to engage in corrective action. Therefore, approval of SRTR as a QCDR would fulfill the objectives of the CPIA provisions of MACRA, which focus on clinical practice and care delivery improvement.

- For MIPS purposes, clinical practice improvement activities must include population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry) and patient safety and practice assessment such as through practice assessments related to maintaining certification.

  As discussed above, suboptimal performance as measured by the SRTR triggers peer review administered through the Organ Procurement and Transplantation Network and also may trigger a requirement that the transplant center undertake corrective action to maintain Medicare certification. Both of these interventions have been shown to improve care delivery and improve outcomes.

<u>*Proposals to Facilitate Approval of SRTR as a QCDR*</u>

In a number of respects, SRTR deviates from the historical requirements imposed by CMS for QCDRs, and we urge CMS to make such modifications as may be necessary to the QCDR requirements to facilitate approval of SRTR as a QCDR. A number of areas that may require increased flexibility are flagged below.

Virtual Groups

Section 1848(q)(5)(I) of the Act requires the Secretary to establish a process to allow an individual MIPS EP or a group practice of not more than 10 MIPS EPs to elect for a performance period for a year to be a virtual group with other such MIPS EPs or group practices for the purposes of fulfilling the quality and value component of MIPS. Under this provision, the performance of each individual in the virtual group is based on the virtual group's performance: All of those in the virtual group will have the same quality and value "scores" for the purpose of MIPS. Thus, it appears that the legislation addresses one of the primary roadblocks involved in approval of SRTR as a QCDR by eliminating the current requirement for PQRS performance to be determined on an individual basis—a feature of the current system that is inimical to the "team approach" used in transplantation.

- In the RFI, CMS seeks comment on whether practitioners in a virtual group and virtual group practices have a unique virtual group identifier that is used for MIPS purposes.

  Response: ASTS would support issuance of a unique virtual group identifier or modifier to be used in conjunction with a physician's NPI and the practice identifier, to be used exclusively for MIPS purposes, and that could be used by transplant teams to ensure that patient outcomes are shared, without individual attribution of results. We note that for virtual groups formed for the purpose of sharing quality performance scores for transplantation it may be appropriate to utilize a variant of the UNOS center code, which is an identifier issued by the OPTN.

How should eligibility, participation, and performance be assessed under the MIPS for voluntary virtual groups?

- Should there be a maximum or a minimum size for virtual groups?

  Response: There should not be a maximum or minimum size for virtual groups.

- Should there be a limit placed on the number of virtual group elections that can be made? If so, how should decisions be made on first come/first serve basis?

  Response: There should not be a limit placed on the number of virtual group elections that can be made.

- Should CMS limit the mechanisms by which quality performance data can be reported by virtual groups to specific methods such as QCDRs or utilizing the web interface?

  Response: Virtual groups should have the same options for reporting quality performance data as EPs reporting through other means (i.e., individual and group practice reporting options, including QCDRs).

- What type of information should be required in order to make a "virtual group" election?

Response: The EP's NPI and the TIN of the EP's group practice (if applicable) should be required, as well as the name of the EP's group practice and billing address. In addition, the duration of the virtual group election and the virtual group's option for reporting quality performance data (including the name or other identifying information of the QCDR to be used, if applicable) should be required.

- Should there be limitations, such as that MIPS EPs electing a virtual group must be located within a specific 50 mile radius or within proximity of each other and be part of the same specialty?

  Response: Limitations on virtual groups should be kept to a minimum. Transplant teams may include EPs from a number of different specialties and, to encourage the formation and accountability of multi-specialty teams, no specialty limits should be imposed. We note that there are already federal regulations that define requirements for inclusion as a member of a specific transplant team—including consideration of proximity to the transplant center—and no further limitations such as regarding proximity should be imposed.

Quality Performance Measures

Generally, to avoid the PQRS payment adjustment, individual EPs and group practices are required to report on a specified number of measures covering a specified number of National Quality Strategy domains. However, the PQRS measures, which are generally "process" rather than "outcomes" measures, are an imperfect "fit" with the types of center-specific measures reported using the SRTR. Implementation of new, more outcomes-oriented quality measures would facilitate approval of SRTR for recognition and approval as a QCDR under MIPS.

We believe that the current PQRS measures and reporting structure do not serve the needs of Medicare patients and that existing measures requirements and reporting mechanisms impose unnecessary and complex reporting burdens on EPs. For this reason, we strongly urge CMS to take this opportunity to completely revise quality reporting measures and reporting mechanisms under MIPS.

In our view, SRTR should serve as a model for other surgical specialties: SRTR incorporates a "team" approach to quality assurance, which more realistically reflects how quality in the provision of surgical services is attained and retained and which minimizes surgeons' incentives to avoid performing surgery on sicker patients whose outcomes may be sub-optimal. In addition, SRTR, unlike PQRS, tracks patient outcomes rather than processes of care, providing patients with helpful information in selecting their health care providers and providing health care providers with clinically useful information.

For these reasons, in response to the queries posed by CMS in the RFI, ASTS believes:

- CMS should not maintain the same or similar reporting criteria under MIPS as under the PQRS.
- CMS should not maintain the policy that measures cover a specified number of National Quality Strategy domains. Rather, CMS should focus on reporting of fewer but more meaningful outcomes measures, especially with respect to surgical procedures. The use of

fewer but more clinically meaningful measures is likely to reduce the number of specialties for which there are insufficient measures available—a major problem under the current PQRS program.

- CMS should utilize process measures in an extremely limited fashion and only when outcomes measures are not available or cannot be reliably implemented or reported.
- CMS should require that reporting mechanisms include the ability to stratify the data by demographic characteristics such as race, ethnicity, and gender.
- CAHPS is not currently useful for transplantation, and even the CAHPS Surgical Care survey is of limited utility, since a host of surgeons, physicians, and non-physician professionals are involved in the care of the patient (other than the surgeon and the anesthesiologist). In fact, the recipient may have had no prior interaction with the transplant surgeon who ultimately performs the transplant. Furthermore, a major aspect of provider/patient perioperative communication and quality of care focuses on immunosuppressive and other medications (but this is not addressed by S-CAHPS). 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.
- The primary barriers to the implementation of meaningful outcomes-based measures under MIPS relate to the lack of resources for the development of the measures and the implementation of registries and other processes for measure reporting. While substantial time and resources have been devoted to formulating and implementing process measures of the type tracked by PQRS, it appears that there are few registries and other reporting mechanisms that focus on outcomes measures. We believe that CMS could provide substantial incentive for the development of more meaningful outcomes reporting processes by affording substantially more flexibility in implementing the QCDR provisions of the Medicare Act by, for example, eliminating the requirement for a minimum number of measures in specific "quality domains"; approving registries that report on meaningful patient outcomes without significant administrative impediments; trusting specialties to define meaningful outcomes through consensus processes; and allowing third party certification of QCDRs that meet relatively broad and flexible requirements.
- We also believe that the lack of accurate and reliable risk adjustment methodologies can be a major impediment to the development of meaningful outcomes-based measures and encourage the agency to invest in research in this area.

Data Verification Requirements for QCDRs and Other Registries

- We understand that data reliability may be an issue for some QCDRs and other registries. However, the data analyzed by the SRTR are collected by the Organ Procurement and Transplantation Network under a contract between HRSA and the OPTN. The OPTN sets and maintains data quality standards and supplies the data to the SRTR for analysis and quality reporting. Therefore, the issue of data reliability is not a significant concern with regard to the SRTR.
- We urge CMS to adopt data submission standards for QCDRs that are consistent with those imposed by HRSA for SRTR.
- MIPS EPs should not be penalized when the data reporting mechanism they have used is subsequently determined to fail CMS' data integrity requirements.

Resource Use Performance Category

While we believe that CMS should implement MIPS in a manner that enables virtual groups to share the same quality scores, it is unclear whether or not virtual groups will have sufficient control over resource utilization to share resource use scores. For example, if (as might be anticipated) some virtual groups are composed of individual physicians or other EPs from various group practices, the individual members of the virtual groups will have to practice within the resource constraints of their own group practices (TINs). For this reason, we urge CMS to implement the virtual group provisions of MACRA in a manner that allows virtual groups for the purpose of quality assessment only, and to enable virtual group members to be included with the members of their TINs with regard to resource use assessment.

We also caution against use of any cost metric that measures all-cause hospital readmissions without accommodating the special circumstances of hospitals that include transplant centers. It is critical to guard against the creation of disincentives to the expeditious re-hospitalization of transplant recipients in the case of potential organ rejection or complications of transplantation, in order to maximize positive outcomes. Therefore, to the extent that CMS includes all-cause rehospitalization rates in the cost category of MIPS, transplant patients should be exempted from the measure.

Clinical Practice Improvement Activities

In the RFI, CMS sets forth a number of categories of activities that may be included in determining an EP's score with respect to the CPIA category of MIPS. For example, CMS suggests a subcategory of "Promoting Health Equity and Continuity," including, for example, (a) serving Medicaid beneficiaries, including individuals dually eligible for Medicaid and Medicare, (b) accepting new Medicaid beneficiaries, (c) participating in the network of plans in the Federally facilitated Marketplace or state exchanges, and (d) maintaining adequate equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales) to provide comprehensive care for patients with disabilities. In addition, CMS also suggests a subcategory of Social and Community Involvement, such as measuring completed referrals to community and social services or evidence of partnerships and collaboration with the community and social services. Both promotion of health equity and social and community commitment are part of transplant surgeons' routine practice, and we support the inclusion of these categories of CPIAs.

However, a number of other subcategories of CPIAs suggested in the RFI appear to be inapplicable to transplant surgeons' clinical practice, and while we most certainly do not object to the inclusion of this subcategory of CPIA, we believe that it is important that CMS take into consideration the applicability of the CPIA subcategories to the various specialties, to make sure that sufficient subcategories of CPIAs are established for all physicians, regardless of specialty.

In this regard, we urge CMS to establish a subcategory of CPIA for "participation in enhanced quality assurance," which may include a wide range of specialty "above and beyond" accreditations, certifications, and training. Examples include leadership development certificate programs (which focus on quality improvement), national evidence-based CME symposia, web-based peer reviewed educational modules, journal based maintenance-of-certification self-assessment programs, and others.

In addition, transplant surgeons and other members of the transplant team are integrally involved in private payer certifications of their transplant centers, and credit should be provided for participation in these activities, which are critical and extremely time-consuming. For example, transplant providers are required as a Condition of Participation in the CMS approval of transplant programs to spend significant time and additional resources dedicated to CMS-defined center-level Quality Assessment and Performance Improvement (QAPI); the regulations for QAPI programs include process and outcomes measures relevant to pre-transplant care, transplant hospitalization, and post-transplant care (measures developed by individual programs based on their specific gaps and opportunities), adverse event management, and other safety and satisfaction endeavors (and CMS surveys, certifies, and provides citations for each center's QAPI programs). We believe it likely that similar specialty credentialing, accreditation, and certification related activities exist in other specialties (although the regulatory standards for transplant programs are unmatched for other clinical programs) and believe it would be appropriate for CMS to establish an "enhanced quality assurance" category under the CPIA MIPS category to encourage participation in these activities.

Another group of activities performed specifically by transplant providers and appropriate for approval as a subcategory of CPIA involves their participation on committees and boards and in other activities of the United Network for Organ Sharing (UNOS) and/or their individual Organ Procurement Organizations (OPOs). These bodies focus on increasing organ donation and transplants, decreasing barriers to access, promoting safety, improving survival outcomes, enhancing ethics of transplantation, supporting innovation, and so on. Providers who contribute to these voluntary activities should receive credit in the category of CPIA.

Finally, we have some concern about whether CMS has the resources necessary to track physician performance under MIPS. We urge CMS to consider "out of the box" solutions that involve contracting with various organizations, such as information clearinghouses, registries, organizations specialized in confirming physician qualifications for hospital and other credentialing purposes, and professional organizations to fulfill some of the responsibilities of implementing the CPIA category of the MIPS, with which CMS has had no prior experience.

Alternative Payment Models

Our reading of MACRA is that the types of entities that meet the MACRA definition of an Alternative Payment Model (APM) are quite limited: Basically, an entity must be participating in a CMS demonstration project (generally through CMMI) or must be an Accountable Care Organization (ACO). Moreover, the legislation requires that ACOs and demos meet certain additional qualifications to become "eligible" APMs, including a requirement that they incorporate quality measures "comparable" to those used under the MIPS quality component and that they incorporate financial risk sharing elements that are more than "nominal."

We strongly urge CMS to interpret the quality measurement and risk sharing provisions of MACRA liberally, in order to ensure that ACOs and the various demonstrations launched by CMMI and other groups within CMS qualify as "eligible" APMs for MACRA purposes. We note that transplant surgeons

interested in pursuing the APM route under MACRA are most likely to qualify if the transplant programs with which they are affiliated are located in hospitals that are ACO participants or if those hospitals are participating in a Bundled Payment for Care Improvement (BPCI) or other bundling demonstration involving transplant admissions. At this stage, transplant admissions are not included in the BPCI, and we urge CMS to make bundled payment arrangements available for transplant admissions to facilitate transplant surgeons' becoming qualified APM participants.

In addition, we are concerned that the thresholds relating to the amount of payment that physicians must receive from APMs to qualify as qualified APM participants may be difficult to meet if these thresholds are strictly applied. For example, a transplant surgeon may receive less than the threshold percentage of his or her Medicare (or non-Medicare) revenue from transplant surgeries and the rest from other surgeries or services related to the provision of care to ESRD patients; however, the hospital—not the surgeon—determines the admissions that are subject to the BPCI. We urge CMS to interpret the thresholds liberally to ensure that physicians who work with a hospital that participates in an APM are considered qualified APM participants under MACRA.

CMS (through CMMI) typically defines the quality measures required for various demonstrations, and the quality measurements required for ACOs are prescribed by regulation. We believe that any quality measures required by CMMI in conjunction with its demonstration projects and those required by CMS for ACOs should be deemed to be "comparable" to those used for MIPS purposes. We further believe that the types of investments typically required for systems to establish ACOs and to participate in CMMI demonstrations (e.g., IT systems, establishment of provider networks, establishment of governance mechanisms and risk and reward sharing systems) are sufficiently costly for CMS to find that these systems bear financial risk for monetary losses under the APM that are in excess of a nominal amounts, for the purposes of qualifying as an APM.

ASTS appreciates the opportunity to comment on the RFI. If you have any questions regarding ASTS' comments, please do not hesitate to contact me or ASTS Executive Director Kim Gifford at *kim.gifford@asts.org* or 703-414-7870.

Sincerely yours,

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