



September 27, 2019

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

Re: CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1717-P)

Dear Administrator Verma:

On behalf of American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed rule for CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1717-P). ASN's more than 20,000 members are leading the fight to prevent, treat, and cure kidney diseases and advocating for the highest quality care for the 37,000,000 Americans and more than 850,000,000 people worldwide affected by kidney disease. In keeping with ASN's mission, we applaud the Trump Administration for creating an ambitious agenda for kidney health through the Executive Order on Advancing American Kidney Health, many aspects of which are addressed in this proposed rule. ASN strongly supports these goals and stands ready to work in collaboration with the administration, Congress, and other stakeholders to achieve success.

Organ Procurement Organization (OPO) Metrics

The society appreciates the opportunity to comment on potential changes to OPO outcomes metrics, an important set of changes the society has long supported. More recently, the society was pleased to see that President Trump included OPO outcome metric reform in his Executive Order on Advancing American Kidney Health. ASN believes that reforming the current system of OPO performance oversight is necessary to enable the Advancing American Kidney Health goal of doubling the number of kidneys available for transplant by 2030 as well as to approach the proposed target transplant rate described in the ESRD Treatment Choices proposed model. The request for information regarding potential changes to organ transplant organization and transplant center regulations is an important first step in this process, and the society hopes that this is followed closely by proposed and final rules to swiftly enact these crucial policy revisions.

CMS proposes to revise the definition of "expected donation rate" to state that the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and Donor Service Areas (DSAs) DSAs, correcting a previous oversight and aligning this definition with the Scientific

Registry of Transplant Recipients (SRTR) definition. ASN does not oppose this change, or the recommendation to use 12 months of data the first year and 36 months of data after the 2022 recertification cycle, “if there are no other changes to the OPO outcome measures,” as the proposed rule states, per se.

However, ASN also particularly appreciates the request for information regarding potential changes to organ transplant organization and transplant center regulations and the society hopes that there are significant changes to current OPO outcome measures in the near future.

The current OPO outcome measures do not accurately or reliably reflect an OPO’s performance. OPOs are currently evaluated using metrics that are neither objective nor verifiable, because the denominator is based on self-reported data. The key donation metric—the conversion rate of eligible donors—is subject to interpretation because OPOs themselves declare how many eligible donors there were, essentially self-selecting their own denominator for the performance metric.

(The observed-to-expected organ yield metric is also problematic, because it does not give credit to OPOs for pursuing single-organ donors.) There are many dedicated, hardworking people in the field of organ procurement nationwide. But a system that is based on self-reported data is inherently at risk for inaccuracy, either by over-reporting conversion or under-reporting eligible donors.

Data exist to support this concern. For example, in 2006, CMS revised OPO metrics, placing a greater emphasis on the “conversion rate.” In the next decade, OPOs reported conversion rates rose from 54% to 82%, yet the absolute number of donors recovered annually over that period was relatively flat [https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf].

Besides precluding accurate assessment of individual OPOs’ performance, the current system results in an inability to compare OPO performance; this reflects the lack of a consistent data standard for the denominator. Consequently, it is impossible to objectively or conclusively determine which OPOs should be seen as the standard bearers for other OPOs to emulate and implement their best practices. The inability to make meaningful comparisons and derive lessons learned is a major hindrance to the field—and, ultimately, to patient access to transplant. Deeper discussion of processes that lead to the end result across phases can be helpful. As one example, Mid-America Transplant has applied the Baldrige model of integrated performance and has been called upon to teach nationally to help other OPOs improve performance; transparent, verifiable data would enable identification of top performers and empower them to share best practices [Mid-America Transplant Services Wins Baldrige Award <http://www.aopo.org/mid-america-transplant-services-wins-baldrige-national-quality-award/>].

In order to address the organ shortage and optimize organ procurement efforts in every region of the country, we must have verifiable, consistent data regarding performance. Only when we truly understand actual performance and have the ability to make meaningful comparisons can we hope to significantly or systematically improve it. The current lack of such data impedes progress on behalf of the nearly 100,000 Americans on the kidney wait list.

CMS asks commenters to describe the current impacts or consequences of current outcome measures on OPO performance. Unfortunately, the current outcomes measures have very little consequence on OPOs’ performance because they are not enforceable. The lack of reliable data not only impedes our ability to identify best practices and make meaningful comparisons across and between OPOs but also effectively nullifies CMS’ ability to hold OPOs accountable

for poor performance. Indeed, no OPO has ever lost its contract, and when CMS has attempted to do so, the lack of validity of the performance metric data is cited to prevent action. For performance metrics to be meaningful drivers of OPO performance improvement and performance accountability, CMS needs to implement objective, verifiable metrics that utilize consistent data across OPOs. To be clear, ASN is advocating for the availability of better data to understand—and ultimately improve—OPO performance. Rescinding contracts is not an end goal per se: the end goal is to optimize organ recovery on behalf of patients, but in order for CMS' authority to be effective in driving rapid improvements it is imperative that the agency have access to transparent, reliable data. Ideally mechanisms for leadership changes and rapid improvement efforts would be the first lines of action should underperformance be identified.

CMS also asks commenters to describe the current impacts or consequences of existing outcome measures on the availability of transplantable organs. Unsurprisingly in the context of the absence of reliable performance data, organ procurement efforts are not operating with optimal efficiency nationwide. Research suggests that OPO performance varies substantially, and that this variation is not due to regional differences in the causes of death or local demographics. Research suggests that up to 28,000 organs that could be transplanted are not procured every year [The Bridgespan Group. "Reforming Organ Donation in America." May 2018]. While OPOs have recently highlighted gains in the number of organs procured, [[JAMA](#), 2019 Aug 8. doi: 10.1001/jama.2019.9187] these gains have been almost exclusively due to the increase in opioid-related deaths and not reflective of improved OPO performance [N Engl J Med 2018; 378:1943-1945 DOI: 10.1056/NEJMc1802706].

It is indisputable that our deceased-donor organ donation system is not operating at utmost efficiency. The lack of transparent, verifiable data regarding organ procurement activities is a major limitation to improvement in this critically important effort. To best serve the more than 100,000 patients waiting for an organ transplant, we must collectively acknowledge this unfortunate reality and swiftly move to implement better metrics based on consistent data nationwide.

ASN recommends that CMS implement the metrics described and validated in the July 2017 paper "Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States" in the *American Journal of Transplantation* as a replacement for the current outcome measures for OPOs (percent of eligible donors and conversion rate, whose significant limitations are described above). These metrics are 1) donation percentage (percentage of possible deceased-donors as a percentage of in-hospital deaths among patients 75 years of age or younger with a cause of death consistent with organ donation who become actual donors; and 2) organs transplanted per possible donor. These measures were one of several that were thoroughly examined in the July 2017 American Journal of Transplantation paper and were found to be a significant improvement over the current eligible death metric [American Journal of Transplantation 2017; 17: 3183–3192].

As lead author David Goldberg, MD, and his colleagues accurately summarize, "compared to the current metric that relies on eligible deaths, the benefits of our proposed donation metric are that it:

1. Does not rely on self-reported data
2. Utilizes a uniform process of estimating the donation potential within each donor service area
3. Includes potential DCD donors that are excluded from the eligible death definition, and

4. Provides a reliable year-to-year measure of OPO performance to track changes in performance.”

ASN also highlights that this can be easily implemented without requirements for the collection of new data, as the data for this metric are already available from the Detailed Mortality File of the Centers for Disease Control (CDC). As such, it aligns with the objectives of the Meaningful Measures initiative and goals of Patients Over Paperwork. Over time, ASN would also recommend further validation efforts and endorsement and continued review of these measures. Working towards National Quality Forum (NQF) endorsement is also an important step, and while ASN is not recommending waiting for formal NQF before moving ahead with this metric, the society recommends it be stewarded and brought forward for NQF consideration in the future.

Some stakeholders have proposed that a metric accounting for ventilator-related deaths is the ideal alternative to the current OPO metric. For several reasons, ASN does not recommend that approach. First, the administrative and technical burden required to implement this metric would be massive, and potentially infeasible.

The lack of interoperability is a challenge that OPOs, hospitals, and transplant centers confront—along with the rest of medicine—and which creates unique challenges for identifying deaths on ventilator for organ procurement performance measurement. For example, the most common medical record system, EPIC, has inconsistent documentation for ventilation and does not currently have a tool to generate a report of ventilator parameters. To be useful for measurement purposes, this information requires consistent and accurate documentation; in many cases, it is documented incompletely at best and sometimes not at all. EPIC is just one example of a common medical record not well-positioned to implement a metric of ventilator deaths, but the reality is that many hospitals do not have an electronic medical records, or have other electronic medical records, particularly for intensive care patients.

In lieu of having deaths on ventilator information readily available in an interoperable electronic medical record format, using it in performance measurement would require painstaking manual chart review by a medical professional and would have to be required in every hospital in the country. In the future, dialogue with electronic medical records vendors to attempt to articulate a clear, reproducible way to identify ventilation dates could be a worthwhile effort, but such an effort should not be a substitute for significant improvements attainable with currently available data sources and technologies. Eventually, the acquisition of death on ventilator data could be viewed as an improvement, and ASN would support that discussion in the future. As part of these efforts, consensus regarding which definition of ventilated deaths to use would first need to be achieved—either the National Surgical Quality Improvement Program definition or the more complex Agency for Healthcare Research and Quality definition.

Second, the level of precision that could be obtained by requiring all hospitals to report deaths of all inpatients placed on a ventilator is not actually necessary to improve performance, even if it helps determine medically suitable organ donation potential with greater precision: the international standard to assess organ procurement rates is per million people in the population (PMP).

The PMP metric does not have nearly the level of detail the Goldberg metric that ASN is recommending CMS implement—such as including only patients 75 years of age or younger and whose death was consistent with organ donation—yet is the gold standard in virtually every other country. Attaining a denominator that contains exactly every single patient who is a potential donor and not one single patient who is not a potential donor is an unnecessary level

of perfection. Much more important is using a denominator that is consistent across OPOs, is feasible to implement, and can enable assessment of and comparisons between OPOs. While the metric will include some patients in the denominator who are not suitable organ donors, because every OPO will be subject to some misclassification and there is little reason to believe that this misclassification will differ substantially by region, the effect of this misclassification should be mitigated across OPOs nationwide.

Missing in this discussion of hospital data is the critical role of the donor hospital. ASN suggests that CMS also consider what expectations it asks of donor hospitals and to consider their important role in the overall transplant ecosystem.

Third, we believe that the continued pursuit of a perfect OPO metric will limit potential progress that can be made in kidney donation in the next several years. The Goldberg metric, while not offering a perfect assessment of every possible donor (and no patients who are not suitable candidates), is much better than the current standard, and a far better than using eligible deaths. The key point is that when there is a very large performance gap—as is the current case—it is not necessary to have a perfect metric to drive needed and significant performance improvements while simultaneously minimizing unintended consequences. When the performance gap is extremely low, the accuracy of measurement is more important. Right now, with what we believe there is a considerable performance gap, we believe some imprecision is not only acceptable but a major improvement over the status quo. This calculus will need to be revisited as improvement occurs but at this time the two metrics proposed by Goldberg, et al are a readily available tool to address a significant performance gap.

In conclusion, ASN strongly recommends that CMS swiftly replace the current OPO metrics with two new metrics, outlined by Goldberg and colleagues: 1) donation percentage (percentage of possible deceased-donors as a percentage of in-hospital deaths among patients 75 years of age or younger with a cause of death consistent with organ donation who become actual donors and 2) organs transplanted per possible donor. Again, ASN also believes that putting these metrics through the NQF process expeditiously would be important.

Transplant Center Conditions of Participation

As CMS alludes to in the request for information, patient access to organs for transplant is not a one-sided equation: increasing deceased donation requires a partnership of OPOs, transplant centers, patients and families. If the goal is to procure and transplant (rather than procure and discard) more organs from less ideal donors, transplant centers and patients need to be willing to accept them. Today, transplant centers that are worried about their outcome numbers are in many cases overly selective, passing on organs that may benefit patients. The disconnect between patient survival rates on dialysis (~85% one-year and ~60% five-year survival) and the survival rates that transplant centers are asked to achieve (~95% one-year survival rates) is enormous.

It is very possible that, in not transplanting more patients, transplant centers may be increasing overall mortality due to the very high death rate seen in maintenance dialysis. The unintended consequence of transplant centers working to maintain such lofty outcomes is that many patients who are not truly ideal candidates are not given the chance to receive a transplant (and many organs that are not ideal are discarded)—with the patients left to face far worse survival odds on dialysis. This ‘risk averse’ approach is not patient-centered, and ASN commends CMS for looking for opportunities to optimize and harmonize requirements for all stakeholders.

CMS is well aware of the unintended consequences of using one-year patient death and graft survival for high-stakes, punitive consequences including center certification. These performance standards are a disincentive to non-standard organ acceptance. ASN was pleased to see that CMS proposed adjusting the flagging associated with the one-year outcome performance levels in the fall of 2018, and continues to believe that finalizing that proposal would have a positive effect on patient access to transplantation by creating latitude for centers to be less risk averse, transplanting patients who are good but not perfect candidates and allowing them to the option of transplant rather than dialysis. It would also address the current conflict of motivation that exists between OPOs and transplant centers, with the former incentivized to procure and place, and the latter incentivized to accept for placement only the most ideal, low-KDPI score kidneys. We urge CMS to finalize that proposed change as soon as possible.

Related, ASN also suggests that CMS consider an exemption scenario in which either higher-risk patients or higher-risk kidneys (or a combination of both) be exempted from transplant centers' denominators for performance metrics. Similar to the COIIN project, this approach would create latitude for transplant centers to be less risk-averse and transplant some patients who would not be considered candidates for transplant under today's stringent performance expectations.

ASN also observes that, while the care of higher risk recipients or higher risk organs is more expensive, and CMS does not adequately reimburse for more costly, higher risk care (Axelrod/Lentine *Am J Transpl* 2017 PMID: 27565133). The society strongly recommends that CMS explore higher payments for these higher risk kidneys and patients, who are more resource-intensive to care for but who also may be likely to benefit from having access to a deceased-donor kidney transplant versus continuing with dialysis. This change would create greater harmony between the objectives OPOs are asked to achieve and the objectives transplant centers are asked to achieve—with the primary beneficiaries of this change being patients with a higher likelihood of getting a kidney.

It is appreciated in practice, as well as formally documented, that care of higher risk donors and recipients is more expensive for centers. Risk of financial loss is a disincentive to the acceptance of both higher risk donors and higher risk patients. As CMS and the administration work to increase access to transplantation as part of the Advancing American Kidney Health initiative, the most significant opportunity for increased organ placement is in the "lower quality"/higher risk category of kidneys, which are at present often either not procured or discarded.

Today, the compensation for kidney transplantation is a global fee that covers three months of care. However, individuals who receive organs that are of lower quality (or are a higher-risk patient), take more resources such as a longer length of stay and more inpatient complications, as well as more intensive care in the outpatient post-transplant care setting. As highlighted in the *Report of the National Kidney Foundation Consensus Conference to Decrease Kidney Discards*, deceased donor kidney transplant in patients with Estimated Post Transplant Survival (EPTS) scores of 85-100 (indicating a shorter expected survival) was associated with \$5,257 more in costs but only \$2,475 of additional Medicare payments. [Cooper et al *Clinical Transplantation*. 2019;33:e13419.] Additionally, these candidates are typically offered high KDPI organs, and the challenges of using these higher risk kidneys further compounds expected losses for transplant centers.

Having a payment system into account that additional care would be helpful in programs having the ability to have in place what is needed to optimize outcomes for individuals receiving higher

risk (aka lower quality) kidneys. Over time, an understanding of what outcomes norms and best practices for this higher-risk group would be developed. Alternatively, CMS could develop a set of positive rewards for listing higher-risk patients (or transplanting higher-risk patients) and transplanting higher-risk organs, instead of a punitive system.

In summary, overly stringent, inflexible transplant center outcome standards are key barriers to both use of higher-risk organs that could benefit patients (which are currently discarded) and the decision to transplant higher-risk patients who will otherwise remain with dialysis (with a greater likelihood of death and of lower quality of life). As CMS addresses OPO incentives by revising their outcomes metrics with the goal of optimizing organ procurement, ASN strongly urges CMS to explore multiple other avenues, described above, to revise transplant center metrics and performance thresholds to create latitude for centers to optimize patients' access to transplant.

Again, thank you for the opportunity to provide input on these important aspects of transplant care in the United States and for your attention to these issues. To discuss ASN's feedback regarding the proposed rule or strong support for the Executive Order on Advancing American Kidney Health, please contact ASN Director of Policy and Government Affairs Rachel N. Meyer at rmeyer@asn-online.org or 202-640-4659.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Rosenberg", with a stylized flourish at the end.

Mark E. Rosenberg, MD, FASN
President