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Mss. Wilson and Corning:

The OPTN is pleased to submit a response to the Proposed Revisions of Organ Procurement Organizations Conditions of Coverage (Section XVIII) as published on Aug. 9, 2019.

The metrics used to assess performance should be based on data that is timely, actionable, and consistently reported. The OPTN, through its Membership and Professional Standards Committee (MPSC), uses metrics to support member organizations' performance improvement efforts prior to CMS initiation of the decertification process. To do so, the data used for regulatory metrics need to be available in a timely manner and accurately reflect the performance of the system, which includes the organ procurement organizations (OPOs) responsible for deceased donor organ recovery.

XVIII.3.B. Proposed Revision of the Definition of "Expected Donation Rate" (p. 39596)

CMS is proposing to correct an oversight in the regulations that displays outdated risk adjustment factors to be used in the expected donation rate model. As a result of that change, CMS is proposing to "...calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2020). After the 2022 recertification cycle, and if there are no other changes to the OPO outcome measures, we would assess OPO performance based on 36 months of data." This would also shorten the data cycle for this metric to 12 months when regulation requires 36 months of data over a 48 month cycle. Donor activity varies from month to month, quarter to quarter. One of the reasons a 36 month measurement period was implemented was to account for this variability and avoid incorrectly identifying OPOs as failing the metric due to normal fluctuation in activity rather than underlying performance concerns. For these reasons, the OPTN does not support the use of a shortened 12-month metric as an appropriate application for this measure. The choice of an appropriate evaluation window for calculating OPO performance statistics should carefully take into account both the desired statistical precision of the estimate (and likelihood of false positives) as well as the goal of accurately characterizing *current* institutional performance by relying on the most recent data as much as feasible.

XVIII.3.C. Request for Information Regarding Potential Changes to the Organ Procurement Organization and Transplant Center Regulations (p. 39597)

To assess OPO performance, the national transplant system needs to determine if an OPO is maximizing their donation potential. To do this there needs to be accurate and reliable measures of conversion of suitable deaths to donors and organs transplanted from actual donors. CMS currently evaluates OPO performance in converting potential to actual donors using an observed to expected donation rate. The quality of an expected donation rate is highly dependent on the data used to calculate the denominator of this metric. If the data available accurately reflect the donation potential being measured, and contain granular enough information to risk adjust, this could act as a solid foundation to assess OPO performance on converting deaths to donors. The underlying data and risk adjustment should reflect the currently reality and be flexible enough to adjust to changes in practice as well as the unique composition of the OPO's potential donors.

It should also be noted that the definition of "eligible death" currently in use by CMS for performance monitoring is an overly narrow definition of donor potential as it does not include post-circulatory deaths. In an era in which nearly 20% of deceased organ donors are post-circulatory death (DCD) and DCD is repeatedly identified as one of the biggest opportunities for donation growth, a more inclusive denominator for assessing OPO performance is needed. Though the CMS conversion rate metric adds 1 to both the numerator and denominator in cases of successful DCD donation, unsuccessful realization of potential DCD donors remains unaccounted for by the metric. Altering the donation rate calculation to account for circulatory deaths that had the potential to be donors would likely provide the system a more accurate picture of donor potential.

The first proposed measure of OPO performance in the Proposed Rules is "actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation." CMS proposes the use of a dataset from the Centers for Disease Control and Prevention (CDC) Detailed Mortality file to calculate the denominator for this metric, an assessment of donor conversion. The CDC dataset has the benefit of being an independent, publically-available source of data as its basis. The OPTN agrees that using an independent, publically-available source of data that can apply definitions broadly *and* that offers a complete clinical picture of a potential deceased donor is more likely to result in more consistent and accurate assessment of donor potential. However, use of the CDC Detailed Mortality File, as proposed by CMS in this document as the first potential measure for OPO performance, has significant limitations. First, the administration of mechanical ventilation, a prerequisite for deceased donation, is not captured in the death records contained in the CDC mortality data. The probability that a death was a ventilated death is variable based on age, cause of death, etc., and these characteristics may not be consistent nationwide. This could lead to a metric that is not consistently or fairly applied across the country. Second, the data as reported from this particular source is not sufficiently timely to be actionable. For example, the most recent data available from this set is from 2017. More frequently-available data would improve the applicability for performance in today's environment. Third, CDC mortality data lacks the relevant clinical information that may be associated with actual donation potential. Without the ability to link CDC mortality data to OPTN data to identify which potential donors actually became donors, a statistical model-based, risk-adjusted donation rate would not be possible. Finally, the administrative reporting of cause of death codes is known to vary by state, particularly depending on whether death data are

reported through a centralized medical examiner's office versus a local coroner. Such variations could impact the accuracy of a donation metric calculated at the OPO level from this data source.¹

The second proposed measure of OPO performance discussed in the Proposed Rules was "actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation." This metric would not be an accurate reflection of OPO performance on placing organs and the data source follows the exact limitations as the first proposed metric. The age and clinical picture of a potential donor is a large factor in the number of organs that could be recovered and transplanted. Using this metric for OPOs would not assess their organ transplant utilization performance, but rather the quality of the potential donors available, which is not within the control of an OPO. The OPTN instead supports use of the observed-to-expected donor yield metric produced by the SRTR and currently used by CMS as one of the OPO performance measures. This metric is a widely accepted because it takes into account the clinical picture of the donor in determining the expected yield of organs for transplant and is an independent assessment of a different part of OPO performance: organ placement. In contrast, the metrics in the Proposed Rule is highly dependent on the OPO's performance on the first measure (donation rate) and treats all deaths to have the same potential yield, which could produce outcomes not in alignment with current clinical realities.

Finally, it appears that there remains no corrective action process or appeal process for OPOs in the proposed rules, nor does it offer an OPO the opportunity to enter into an SIA to take corrective action after citation and before decertification. This structured performance improvement pathway is inconsistent with current COPs for other CMS certified entities, and is beneficial to the stability of the system. Accordingly, the OPTN recommends the addition of this type of pathway.

OPTN Recommendations

To remove possible biases associated with OPO self-reporting of data in the absence of a precise definition of "potential donor," the OPTN recommends that ventilated death data be transmitted independently, preferably directly from the donor hospitals' electronic medical records (EMRs) to the OPTN with sufficient clinical detail to assess if a death met the proposed definition ("conditions consistent with organ donation").

This recommendation is based on previous publications and research, both from the OPTN and from other stakeholder groups. The Propose and Implement National Standards (PINS) group of the Association of Organ Procurement Organizations (AOPO) collaborated with the SRTR in 2015 to identify a possible new donation metric based on donors per ventilated death. Then, in 2016, the results of their work lead the Health Resources and Services Administration (HRSA) to direct the OPTN to perform a study to assess the feasibility of collecting the data necessary to calculate an objective measure of OPO performance. The results of this study indicated that access to hospital-reported ventilated death data, not currently collected, would offer a strong foundation for accurately extrapolating deceased donor

¹ Warner M, Paulozzi LJ, Nolte KB, Davis GG, Nelson LS. State variation in certifying manner of death and drugs involved in drug intoxication deaths. *Acad Forensic Pathol.* 2013;3(2):231-237

potential. Over the last year, AOPO and the SRTR have also been conducting a pilot study with OPTN Region 8 OPOs to assess the feasibility and utility of collecting uniform, ventilated death data, leveraging lessons learned from the HRSA project.

Most recently, the OPTN's Ad Hoc [Systems Performance Committee](#) (SPC), an interdisciplinary group of over sixty OPO, transplant hospital, and patient and donor representatives, also recommended mandating the direct collection of ventilated deaths from donor hospitals to support OPO performance monitoring.²

Regardless of what metric is used, assessing if an OPO is failing to meet a measure should be determined both empirically and practically. As was done with the SRTR's development of new (Bayesian) post-transplant models and associated MPSC review triggers, a sound approach to identifying underperformance should evaluate the true-positive and false-positive rates, sensitivity, and specificity, of the selected algorithm, with input from the community regarding these tradeoffs. Additionally, the OPTN does not recommend using regulation to specify which variables should be used for model risk adjustment. This does not allow for timely refinements to the models over time to meet the changing landscape.

The OPTN appreciates the opportunity to comment on this important effort and is committed to collaborating with CMS in the development of additional outcome measures.

Sincerely,



Maryl Johnson, President
OPTN Board of Directors

² Neil, H., Overacre, B., Rabold M., Haynes CR. PDF file. "Table 9: OPO Metrics Beyond Organ Yield." *OPTN Ad Hoc Systems Performance Committee Report to the OPTN Board*, 10 June 2019 (p. 9).
https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf