July 16, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

SUBJECT: CMS-5535-P, Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, Federal Register (Vol. 89, No. 97), May 17, 2024

Dear Administrator Brooks-LaSure:

On behalf of our 18 hospitals that performed over 3,031 kidney transplants (597 living donor, 2,434 cadaveric) in the most recent year for which Medicare cost report data is available, the California Hospital Association (CHA) is pleased to provide comments on CMS' proposed Medicare alternative payment model — hereafter increasing organ transplant access (IOTA) model — for kidney transplantation.

The stated goal of the IOTA model is improving the quality of care for people seeking kidney transplants, reducing disparities among individuals undergoing the process to receive a kidney transplant, and increasing the efficiency and capability of transplant hospitals selected to participate. The proposed rule attempts to achieve this goal by testing whether using performance-based incentive payments in the form of upside risk payments and downside risk payments to and from select transplant hospitals increases the number of kidney transplants furnished to patients with end stage renal disease. IOTA would be a mandatory model, requiring participation of 50% of the kidney transplant programs in the U.S., beginning on Jan. 1, 2025, and ending on Dec. 31, 2030. Hospitals whose programs increase the volume of kidney transplants, accept more organs than expected, and perform well across four quality metrics will receive a bonus payment per transplant, while those programs that fall below the threshold will be penalized and required to make a payment to CMS.

While California's hospitals support the goals of the IOTA model — improving the quality of care received by individuals requiring kidney transplantation, reducing inequitable outcomes, and improving the efficiency of the transplant process — there are significant concerns that not only will the IOTA model fail to achieve these goals due to design flaws, but may decrease access to kidney transplantation, negatively impacting patients. Therefore, it is respectfully requested that CMS transition the IOTA model to a voluntary model. These concerns along with select suggested improvements to the model are discussed below.

499 So. Capitol Street SW, Suite 410, Washington, DC 20003 ▪ Office: (202) 488-3740 ▪ FAX: (202) 488-4418

1215 K Street, Suite 700, Sacramento, CA 95814 ▪ Office: (916) 443-7401 ▪ www.calhospital.org

- *Transplant Surgeon and Transplant Nephrologist Judgement*: CMS notes in the proposed rule that a motivating factor for the IOTA model is the variation in acceptance rates for similar organs among transplant surgeons. In response to these concerns 80 percent of the points available in the model are achieved by increasing transplant rates ("Performance Domain" – 60 points), which is in part, as discussed below, a function of increasing acceptance of marginal organs ("Efficiency Domain" – 20 points). The efficiency domain score is based on whether the hospital accepts more organs than expected. Points are assigned using the greater of an achievement score (the kidney transplant program's current performance ranked against all other programs) or an improvement score (changes in performance over time).

  It's worth noting that each kidney transplant program is structured differently in terms of the decision-making process to determine whether to transplant an organ. Many programs have the offer initially screened by a transplant nephrologist and a transplant surgeon. The proposed rule does not contemplate this collaborative decision-making process with both a nephrologist and a surgeon utilized by many programs.

  Transplant nephrologists and surgeons are among the most highly trained and skilled providers in the health care delivery system. On average, it takes approximately 11 years of training, including four years of medical school, five years of general surgery, and two years of transplant fellowship to become a transplant surgeon. The decision to accept a specific organ involves not only the organ's quality in isolation, but factors specific to the patient and that organ. The proposed rule acknowledges this, citing, among other non-organ clinical considerations, donor age, body mass index, diabetic status, hypertensive status, "undesirable" social behavior, and terminal creatine values. When a transplant surgeon or a transplant surgeon and nephrologist decline the offer of a marginal organ, it is done with the patient's best interest in mind and by integrating the patient-specific and organ-specific factors into that decision. The incentives in this model could be construed to interfere with the transplant surgeon's or the transplant surgeon and nephrologist's judgment influencing them to accept an organ that would otherwise be declined. ***Given these concerns about interference with physician judgment resulting in suboptimal outcomes for patients, it is strongly recommended this model should be finalized as voluntary.***

- *Unrealistic Volume Increase Performance Expectations*: The "performance" domain in the IOTA model is worth 60% of the points used to calculate whether a transplant program qualifies for a bonus, must repay CMS (starting in year two), or is in the "neutral zone" (neither receiving a bonus payment nor owing CMS repayment). Only kidney programs that increase transplant volumes by 50% or more will receive the full 60 points.

  Based on the most recent data available (2022), the average California program performed 168 kidney transplants. Assuming this is the highest year in the baseline period, it would be inflated forward to 2025 using the national growth rate in kidney transplants between 2022 and 2023 (~7.2%)[1]. This growth rate and baseline volume implies that for the average California kidney transplant program to receive the full 60 points, it must increase its volumes by approximately 100 transplants in 2025.

[1] CHA analysis of OPTN data as of June 25, 2024; https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

Even with the increased use of marginal organs that prior to the model wouldn't have been used, few hospitals will be able to achieve this type of growth in transplantation volumes. While usable organs are one rate-limiting factor, they are not the only ones. It is unclear how many hospitals — if any — have the operating room capacity, available transplant nurses (who are highly specialized), and other highly skilled support staff to perform 50% more transplant procedures. ***CMS is strongly encouraged to conduct research considering all the constraints on increasing volume before putting forth alternative payment models related to organ transplantation in the future to confirm that this rate of growth is in fact possible for all impacted hospitals.***

Further, given that the first performance year is part of the year 3 baseline, even if this level of growth could be realized in the first year, it is even less likely that it could be safely sustained over the life of the model. As a result, hospitals could incur penalties in the later years of the model because of not being able to sustain a high rate of compounded growth in kidney transplant volume. **In light of these issues with the IOTA model, CMS is encouraged to reduce the growth rates used to assign points in the performance domain so that the growth targets are aligned with what is actually achievable.**

- *Potentially Reduce Excised Organs*: The IOTA model will compel 50% of eligible kidney transplant programs to participate. Further, 20% of the scoring model is based on an "Efficiency Domain" that awards points based on whether a transplant program (and more specifically a transplant program's surgeons) is more likely to accept an organ than is expected.

  In addition to implanting donated organs into recipients, transplant surgeons also recover organs from living and deceased donors and determine their usability. Given the incentives in the model, which will impact approximately 50% of the transplant surgeons in the country, it is reasonable to question whether an unintended consequence of this mandatory model might be a decrease in the availability of marginal organs for transplantation. This outcome is contrary to CMS' goals in proposing the model. ***To mitigate these concerns, CMS should finalize IOTA as a voluntary model.***

- *Duplicative Administrative Requirements*: CMS proposes for each month an organ is offered for an IOTA waitlist patient who is a Medicare beneficiary, an IOTA participant must inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline. CMS also proposes IOTA participants would be required to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every six months that the Medicare beneficiary is on their waitlist. This review may be done on an individual basis in a patient visit via phone, email, or mail.

  Further, CMS has included a measure of shared decision making in the model CollaboRATE Shared Decision-Making Score (CBE ID:3327). The measure will evaluate shared decision making across all clinical encounters, including those related to the transplant process. Given CMS' inclusion of this measure in the model, it is presumed the agency believes the score on this metric will be strongly influenced by the degree to which the patient has been engaged in discussions of organ acceptance criteria. If this is not the case, it raises questions as to why the agency has included this measure in the model.

The IOTA model provisions related to discussing organ acceptance criteria and shared decision making will engage Medicare beneficiaries in their care and align them with their care team. It is unclear how the proposed monthly notification of rejected donor organs improves patient alignment with the care team beyond what is accomplished by these provisions. The monthly notification creates additional, unnecessary expense that will not result in better patient outcomes. ***Therefore, it is strongly recommended that CMS eliminate it in the final IOTA model.***

- *Insufficient Time to Prepare:* CMS proposes the first IOTA model performance period will begin on Jan. 1, 2025. Further, the proposed rule did not indicate which hospitals would be compelled to participate. The agency justifies the lack of time to prepare by stating that the first performance year does not include downside risk. This justification is inadequate.

  In all likelihood, by the time CMS finalizes this proposed rule, hospitals that are compelled to participate will have less than 90 days to implement the most basic processes necessary to comply with the model's requirements. Further, any changes to care processes that might lead to the improvement in transplantation will need to be considered carefully — so as not to negatively impact quality — and will require far more time to implement. This is particularly true in the IOTA model given the proposed rule only commits to providing participating hospitals "no later than 15 days" prior to the start of the first performance year. While hospitals will not be penalized for underperformance in the first year, the results of the IOTA model will be published. Given the lack of implementation time provided if the beginning of the first model year is finalized as proposed, those publicized results will be random, not a reflection of performance related to the model's goals, and misleading to the public.

  Further, kidney transplant programs will incur cost to participate in the model. It is important that hospitals have every opportunity to recoup these costs by performing well enough to earn a bonus. Shortening the implementation period not only deprives them of this opportunity but delays the implementation of the interventions deployed — relative to the start of the first performance year — in response to the model. This will not only limit the detectability of improvements in patient outcomes but also reduce the savings CMS realizes by decreased utilization of Medicare covered dialysis that will result through increased kidney transplantation. ***Therefore, CMS should delay implementation of the model and provide participants at least 12 months lead time from when they are accepted to participate (if voluntary) or informed they are required to participate (if mandatory) before the start of the first performance year.***

- *Quality Domain Proposals Lack Clarity:* Under the "Quality Domain", CMS proposes to include one post-transplant outcome measure, the composite graft survival rate, and a quality measure set that includes two patient-reported outcome-based performance measures (PRO-PM), the CollaboRATE Shared Decision-Making Score and the 3-Item Care Transition Measure, and one process measure, the Colorectal Cancer Screening measure. The Quality Domain would account for 20% of the scoring model – 10% of which would be attributed to the composite graft survival rate metric, and 10% to the other three measures in the quality measure set.

  Hospitals are concerned by the lack of clarity included in the quality domain proposals and raise several questions that should be addressed before the true impact of the measures on performance assessment and quality improvement can be fully considered. As noted above, CMS

proposes two PRO-PM measures that rely on survey administration. However, the proposed rule does not specify how these surveys would be administered or reported. For example, CMS proposes that IOTA participants would be required to administer the CollaboRATE Shared Decision-Making Score to attributed patients once per performance year, at minimum, and report quality measure data to CMS during the survey and reporting windows. CMS does not provide detail on what the specific survey and reporting window would be, nor does CMS specify if the data should be reported at the patient-level or aggregate. CMS also does not provide the measure specifications – should IOTA participants administer the survey on a 5-point scale or a 10-point scale? CMS also acknowledges that the survey instrument does not include questions specific to kidney transplant, and it is unclear if patients would provide responses relevant to care attributed to the model.

Hospitals also have questions about the inclusion of the 3-Item Care Transition measure. CMS suggests that IOTA participants should have experience with the measure because it is a domain of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. However, CMS has proposed to revise the HCAHPS survey to remove these questions beginning Jan. 1, 2025, under the hospital inpatient quality reporting (IQR) program and hospital value-based payment program. In addition, the HCAHPS survey is not typically administered by the hospital, rather, hospitals often rely on a third-party vendor to survey a random sample of adult patients across medical conditions between 48 hours and six weeks after discharge. CMS itself notes in the proposed rule that it chose not to include the HCAHPS survey because it is administered to a random sample of patients and "would present sample size issues for purposes of calculation." Thus, requiring IOTA participants to self-administer a subset of questions that are no longer included in the HCAHPS survey to a targeted group of attributed patients is a significant change from hospitals' current experience with the HCAHPS survey.

Hospitals also have concerns with the composite graft survival rate measure, which would account for half of the quality domain score. The measure is a cumulative measure that would increase each year; the numerator is the total number of observed functioning grafts and the denominator is the total number of kidney transplants completed. There are concerns that because the measure is not risk-adjusted, it could lead to transplant programs being more conservative in transplant selections to achieve better performance on the measure, creating an incentive that is counter to the IOTA model goals to increase access to kidney transplantation. CMS should consider appropriate risk-adjustment to avoid these unintended consequences.

The opportunity to comment on IOTA model proposed rule is appreciated. If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143.

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy