ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS

Saving and enhancing lives through organ, eye, and tissue donation.

October 8, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-1850
Chiquita.Brooks-LaSure@cms.hhs.gov

Dear Administrator Brooks-LaSure:

On behalf of the Association of Organ Procurement Organizations (AOPO), I am writing to seek clarification of certain provisions contained in the December 2020 rule, which finalized several significant revisions to outcomes measure requirements for Organ Procurement Organizations (OPOs). Since the rule's release, we have received several questions from our members including how mergers would work both after the initial certification cycle under new rules, as well as potentially in advance of the rules taking effect for OPOs who may preemptively want to merge in an effort to proactively create efficiencies, increase organ availability, and improve performance. It is our intent with this letter to pose these questions to CMS in the hopes of prompting opportunities for stakeholder engagement on this topic. **It is our goal to help ensure a smooth transition to this new system**. We appreciate CMS' consideration of the attached questions, which are organized by topic.

Having a formal, streamlined process and clear guidance to impending OPO mergers will help to avoid unnecessary expenditure of time and resources on legal and other activities by OPOs that could be directed toward organ procurement, as well as CMS' own staff hours. Moreover, having this guidance in place would help OPOs more easily reach voluntary merger decisions, which as CMS acknowledges in the rule is both preferred and more likely to be successful. For example, within two years of forming New England Donor Services in 2017, organs transplanted from donors in the lower performing OPO increased by 108% and saved the system approximately $3 million in decreased kidney-related costs.[1]

AOPO offers our full assistance to serve as a conduit of information and collaboration with our 48 member OPOs and welcomes further opportunities to discuss this topic. Any questions or requests may be directed to Mark Cribben, Director of Government Affairs, at mcribben@aopo.org or 202-256-7255.

Thank you,

Jann Finn
President, AOPO

Detailed Questions and Topics for Future Guidance and Stakeholder Engagement

1. Merging Donation Service Areas (DSAs)

CMS states in the rule that the regulations "*do not require that DSAs merge when a new OPO takes over [and] in addition to all the possible internal reforms that an OPO could make, OPOs could merge, or service areas could be merged."* To clarify- **CMS will not *require* DSA mergers, but will allow DSA mergers?** If an OPO is to take over an underperforming OPO, it stands to logic that they may wish to streamline operations and mitigate fluctuations in performance caused by a relatively small DSA by combining DSAs. **What sort of criteria would the Agency consider in making this decision? The size of the DSA (and therefore its susceptibility to random variation)? Whether the two regions are contiguous? The number of hospitals within a DSA? What will CMS do if there is a situation in which no OPO is interested in taking over a particular decertified OPO's DSA? If an OPO is decertified for a particular DSA but demonstrates improvement and/or submits a corrective action plan, is there a certain window of time after which it may bid on the same DSA, or is it permanently banned?**

CMS further notes in the rule that "*it would be our preference to not merge DSAs so that we can properly assess whether the new OPO is improving performance in each DSA*." **Is there a certain minimum number of DSAs that CMS wants to preserve in order to ensure an "adequately diversified" market? Has CMS considered how the number of DSAs may impact median and upper quartile calculations for purposes of delineating tiers? Will CMS consider risk corridors for smaller and rural OPOs with small denominators in which a small number of organs (i.e. less than five or ten) would have made a material difference in their tier?**

2. OPO Ownership Structure

CMS says in the rule, "*since DSAs are not required to merge, one OPO could run several DSAs. If an OPO with multiple DSAs cannot reach the outcome measures to be re-certified for one DSA, they will be decertified for that DSA, but could be re-certified for other DSAs (assuming their performance supports it*)." In the past, CMS has required that OPOs merge completely or retain separate staffing and operational structures. **Would CMS take a different approach moving forward? When a new OPO wins a bid to take over a DSA, what types of ownership structures would CMS approve?** There are various potential structures, including (but not limited to) separate governing bodies and staffing with separate DSAs under a parent organization, merging into a single OPO with single governance and staffing but multiple DSAs, or combining OPOs and DSAs. We would appreciate more guidance on what type of structures CMS would allow (or prefer) and how documentation requirements may vary depending on the proposed organizational structure of the merger. Due to a range of factors that make each DSA unique, we encourage CMS to allow a sufficient degree of flexibility so OPOs can make a decision that is best suited for the needs of the local DSA and the donors and recipients they serve. We also note that it is important to leverage the benefits of possible mergers, including efficiencies of scale and scaling successful cultural and operational tactics of the high performing OPO to promote greater efficiency while ensuring a seamless transition that maintains important relationships with regional industry partners and avoids potential workflow disruptions that could jeopardize lives.

Given certification occurs at the OPO level, will CMS evaluate recertification differently moving forward to accommodate scenarios where a single OPO is responsible for multiple, separate DSAs? Will the performance metrics used for recertification be calculated at the OPO or the DSA-level? The answers to these critically important questions will largely determine the true market impact of these policy changes. **For instance, if a single OPO manages multiple DSAs and one falls into Tier 2 or 3 for one of the DSAs, will this negatively impact the OPO's ability to maintain its other existing DSAs, or to take on new DSAs in the future? If an OPO is recertified for one DSA and decertified for another, could the OPO compete for tier 2 or tier 3 OPOs?** CMS states in the rule, *"OPOs that cannot achieve the outcome measures may decide to voluntarily decertify and allow a high-performing OPO take over the DSA… or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA, most likely through a merger or friendly takeover."* **What criteria will CMS consider when selecting an OPO to take over a Tier 2 or 3 DSA? Will CMS use the same or different criteria when it comes to deciding whether a Tier 2 OPO be allowed to retain its own DSA? Will there be an opportunity to appeal Tier 2 decisions?**

3. Performance Evaluation: Timing and Process

Will CMS evaluate mergers that are proposed prior to the 2026 recertification cycle differently than those after? Will there be a certain timeframe within the decertification cycle when mergers must occur? If a merger occurred during or after the reporting year, will the OPOs and/or the DSAs be evaluated separately or jointly for purposes of recertification? We would greatly appreciate additional guidance in this area, including (but not limited to) a detailed visual timeline of how CMS would address mergers that occur within each of the four years of the recertification cycle. CMS states in the rule that for purposes of distinguishing between tiers, "*the percentiles are calculated based on the number of OPOs in the year prior to the reporting year*." How will the **number of mergers in the year between assessment calculation and the decertification year affect tier assignment?**

CMS states in the rule that "*if an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available*." **Does this mean that OPO would be evaluated on a different 12 months of data than all other OPOs? Could this 12 months span multiple calendar years?**

How long after a OPO is marked as Tier 2 or 3 will the bidding process last? After a winning OPO candidate is selected, how long will the OPOs have to take-over the operations in the DSA of the decertified OPO? Will there be a defined transition period? We appreciate that CMS notes in the rule that: "*careful planning and implementation of OPO de-certifications and OPO DSA competitions could ease such transitions*" and urge the Agency to allow sufficient time for planning to ensure involuntary transfers that result from decertification or competition are as successful and seamless as possible. Successful consolidation of this magnitude requires significant management, cultural, staffing and workflow changes, as well as likely could require approval by the state's Attorney General or other state agencies considering the charitable nonprofit corporate status of OPOs. Altogether, this typically entails a multi-year process to be done well, likely 3-4 years.

Will the Scientific Registry of Transplant Recipients (SRTR) be validating CMS' calculations? AOPO believes this would be an important way to help ensure transparency in the process and get buy-in from OPOs. **Will CMS share the donor potential of all OPOs broken down by DSA or county level?** This would greatly streamline the process of having to make individual requests to the Centers for Disease Control (CDC) for raw data, reducing burden not only for individual OPOs but CDC staff as well.