

Congress of the United States

Washington, DC 20515

November 2, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

We write today regarding the Centers for Medicare & Medicaid Services (CMS) final rule, titled, [“Medicare and Medicaid Programs: Organ Procurement Organizations \(OPO\) Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule,”](#) (OPO Final Rule).

OPOs are organizations responsible for evaluating and procuring organs for transplant from deceased donors. The rule revised the method by which CMS measures the performance of OPOs for purposes of recertification. Effective for the 2026 recertification cycle, OPOs will be measured every year on their relative performance on two outcome measures – (1) Donation Rates – the number of organs from the donation service area (DSA) that are donated as a percentage of potential donors; and (2) Transplantation Rates – the number of organs from the DSA that are transplanted as a percentage of potential donors.

The Final Rule is complex, and accordingly, there are numerous unanswered questions regarding how this process will work relating to the ground rules for competition, the process that will be followed for OPOs that want to acquire decertified OPOs, and how to engage in proactive mergers. It is urgent that CMS implement the OPO Final Rule effectively, without weakening standards put in place to protect patients and without delay.

Notably, this process is entering a high level of activity as the decertification of OPOs in 2026 is based on calendar year (CY) 2024 performance, and OPOs are still without guidance from CMS regarding the details of how the OPO recertification and competition processes will be administered.

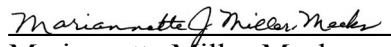
We request that CMS immediately prioritize this issue and provide comprehensive guidance regarding how the final rule will be implemented. We respectfully request answers to the following questions:


1. Is CMS considering any policies to help ensure successful transitions, so that all patients are served by high performing OPOs?
2. If no OPO seeks to assume the operations of a decertified OPO’s DSA, how will CMS decide to which higher-performing OPO to assign that DSA? Conversely, how will CMS determine which of several high-performing OPOs interested in taking over a newly opened DSA will be selected?


3. After a winning OPO candidate is selected, how long will the OPO have to take over operations in the DSA of the decertified OPO? Will there be a defined transition period?
4. Will there be a certain timeframe within the decertification cycle when mergers can or must occur?
5. If a merger occurs during or after the reporting year, will the OPOs and/or the DSAs be evaluated separately or jointly for recertification?
6. Suppose a single OPO manages multiple DSAs, and one falls into Tier 2 or 3. Will this negatively impact the OPO's ability to maintain its other existing DSAs, or to take on new DSAs in the future?
7. Will CMS consider offering time-limited protections to permit OPOs that take over another DSA enough time to get improvements in place without jeopardizing the higher tier work that is taking place in their OPO?


We appreciate your attention to this request.


Sincerely,



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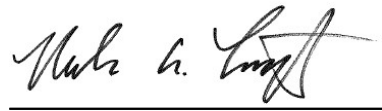
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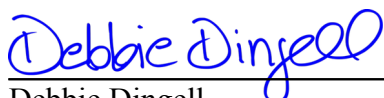
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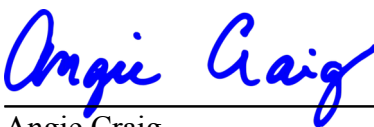
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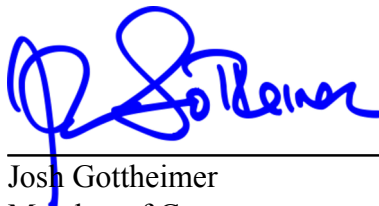
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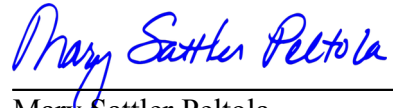
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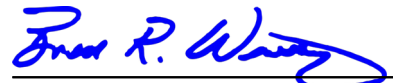
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