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,

Mariannette Miller-Meeks, M.D.
Member of Congress
Mark Pocan  
Member of Congress

Earl L. "Buddy" Carter  
Member of Congress

Robert E. Latta  
Member of Congress

Russ Fulcher  
Member of Congress

Donald Norcross  
Member of Congress

Don Bacon  
Member of Congress

Jefferson Van Drew  
Member of Congress

Donald M. Payne, Jr.  
Member of Congress

Diana Harshbarger  
Member of Congress

Suzan K. DelBene  
Member of Congress

Nicholas A. Langworthy  
Member of Congress

Dean Phillips  
Member of Congress

Bill Pascrell, Jr.  
Member of Congress

Thomas H. Kean, Jr.  
Member of Congress

Mike Carey  
Member of Congress
Brian Fitzpatrick  
Member of Congress

Susan Wild  
Member of Congress

Michael C. Burgess, M.D.  
Member of Congress

Debbie Dingell  
Member of Congress

Vern Buchanan  
Member of Congress

Pete Stauber  
Member of Congress

Bonnie Watson Coleman  
Member of Congress

Angie Craig  
Member of Congress

Josh Gottheimer  
Member of Congress

Jen A. Kiggans  
Member of Congress

Gregory F. Murphy, M.D.  
Member of Congress

John Rose  
Member of Congress

David J. Trone  
Member of Congress

A. Drew Ferguson IV  
Member of Congress

Carol D. Miller  
Member of Congress
<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daniel T. Kildee</td>
<td></td>
<td>Member of Congress</td>
</tr>
<tr>
<td>Ronny L. Jackson, M.D.</td>
<td></td>
<td>Member of Congress</td>
</tr>
<tr>
<td>Mary Sattler Peltola</td>
<td></td>
<td>Member of Congress</td>
</tr>
<tr>
<td>Michael Guest</td>
<td></td>
<td>Member of Congress</td>
</tr>
<tr>
<td>Monica De La Cruz</td>
<td></td>
<td>Member of Congress</td>
</tr>
<tr>
<td>Brad R. Wenstrup, D.P.M.</td>
<td></td>
<td>Member of Congress</td>
</tr>
</tbody>
</table>