Illinois Health and Hospital Association

February 4, 2026

On Jan. 30, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that updates conditions of coverage for Organ Procurement Organizations (OPOs), strengthening federal oversight of these organizations and increasing the number of viable organs that reach patients in need. Given the significant operational changes proposed for OPOs and the potential impact on hospital organ donation and transplant processes, please submit any feedback for incorporation into a potential IHA comment letter to Lia Daniels at ldaniels@team-iha.org by Mar. 13. Comments may also be submitted here by Mar. 31, 2026.

Proposed changes would remove barriers to terminating an underperforming OPO's contract and define conflicts of interest to increase accountability, clarify how to certify new OPOs, modify the designation and appeals processes for OPOs, and alter key definitions that define OPO practices, among other changes. CMS is seeking feedback from hospitals on ways current electronic notification requirements for hospitals could be leveraged to provide automated donor referrals, and any best practices hospitals may be able to share on leveraging technology for automated referrals for future OPO implementation.

CMS proposed changes to definitions, including:

- Modify transplant "adverse events" to remove examples, as they are being interpreted as an exhaustive list of instances that can trigger individual analyses and changes to OPO practices;
- Modify "donor" and "organ" to remove the pancreas when solely used for islet cell research without a transplant, as this research has been used to mask OPO performance of overall successful transplants;
- Newly define "medically complex organs and donors" (including donors who have HIV+ or hepatitis C, are over 70, or are young with deteriorating health conditions) to encourage more organ procurement, while seeking feedback on criteria that should be used in the definitions; and
- Newly define "unsound medical practices" as OPO failures that create imminent threat to health and safety, to ensure these failures are addressed appropriately.

CMS also proposed changes to provide greater flexibility for OPO expansion and oversight, including:

- Permit CMS to designate an OPO for more than one Donor Service Area (DSA);
- Clarify when CMS may seek voluntary or involuntary termination of an OPO's designation, and may separately assign another OPO to that DSA without a competition;
- Assess an OPO's performance in different DSAs separately and permit OPOs to withdraw from a DSA for underperformance without requiring the organization to leave other DSAs or end its agreement with CMS;
- Address all instances when a DSA is open for competition to increase oversight and accountability of OPOs;
- Shift public notice of OPO de-certification and when a new OPO will be designated for the DSA from the OPO to CMS;
- Outline factors CMS should consider when permitting certification of new OPOs;
- Clarify when OPOs may seek an appeal for de-certification, revise the timeframes for different stages of the appeals process, and reduce the number of days an OPO may request a hearing to reduce disruptions in organ procurement activities;

- Limit the licensure requirement for OPO Medical Directors to only one state where they provide services, while expanding minimum personnel qualification standards for other OPO staff, like requiring staff that provide clinical services must have in-state licensure or certification;
- Create new documentation requirements for organs procured by OPOs for research to foster OPO accountability; and
- Outline ways that conflicts of interest (COI) are handled by OPOs, including whether CMS should develop standardized requirements related to COI policies and procedures, whether CMS should review OPO COIs, and standards CMS should use to determine if a conflict exists.

The proposed changes seek to complement the Health Resources and Services Administration's (HRSA) ongoing modernization of the national organ transplant system. For questions or comments for IHA on this proposed rule, contact Lia Daniels at ldaniels@team-iha.org.

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