Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Issues Final Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage

The Centers for Medicare & Medicaid Services have issued revised Conditions for Coverage for Organ Procurement Organizations (OPOs) "to clarify outstanding procedural questions and provide additional operational flexibility for OPOs to achieve high performance resulting in the successful procurement, distribution, and transplantation of more life-saving organs. This rule revises definitions, revises the designation requirements for OPOs, clarifies when an OPO's service area is open for competition, and updates the process for appeals."

A display copy of the 171-page rule, scheduled for publication on November 3, is available at: https://public-inspection.federalregister.gov/2026-22381.pdf. These regulations are effective 60 days after date of publication in the ***Federal Register***.

CMS estimates that this final rule will cost approximately $16.5 million in the first year and $7.9 million annually thereafter. There are currently 54 OPOs that are responsible for identifying patients who may become prospective donors and recovering organs from deceased donors in the United States.

Comments

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Key Provisions for Strengthening Quality, Safety, and Oversight

Adverse Events and Quality Assessment and Performance Improvement (QAPI)

The rule removes the examples currently listed in the definition of "adverse event" and adds a revised list to the QAPI requirements. All OPOs must have QAPI programs that use data to monitor and improve their own performance. OPOs are specifically required to have policies for identifying, reporting, analyzing, and preventing adverse events that occur during the organ donation process. "This change gives clear information so that all OPOs can act to prevent adverse events, investigate all adverse events, and take appropriate action to prevent future similar events." CMS is finalizing the "adverse event" definition as proposed. (Page 22)

Pancreata Used for Islet Cell Research

CMS is finalizing as proposed the definition of "donor", at § 486.302,as a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual will also be considered a donor if only the pancreas is procured and is used for islet cell transplantation or for islet cell research. Additionally, CMS is finalizing as proposed the definition of "organ" as a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for islet cell transplantation. (Page 27)

Medically Complex Donors and Medically Complex Organs

CMS is NOT finalizing the following definitions: "Medically complex donor" and "Medically complex organ". Additionally, CMS is not finalizing the corresponding QAPI requirement. (Page 27)

Unsound Medical Practices

The rule defines "unsound medical practices" as failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures. (Page 38)

Requirements for Certification (§ 486.303)

CMS proposed to remove § 486.303(e), which conditions OPO certification on an entity having been re-certified as an OPO from January 1, 2002, through December 31, 2005. CMS is finalizing its proposal. (Page 42)

Designation of One OPO for Each Service Area (§ 486.308)

CMS is finalizing its proposed changes to § 486.308 with modifications to paragraphs (a)(2), (3), and (4). CMS is modifying paragraph (a)(2) to add "except as noted in paragraph (4)" to include an exception to opening a DSA for competition. CMS is modifying paragraph (a)(3) to add regulatory references "§ 486.316(d)" and "§ 486.308(a)(4)" to the paragraph to identify all instances when CMS may assign a DSA to an organ procurement organizations (OPOs). In paragraph (a)(4), CMS is removing the provision that would open the DSA for competition after assigning a DSA to an OPO. Additionally, CMS is modifying the first sentence to indicate that it would select a single OPO when assigning a DSA. CMS is also modifying § 486.316(a)(2) to address concerns of commenters to ensure that an OPO is not disproportionately impacted in the event an OPO's performance decreases or fails to improve after being assigned a DSA by CMS. (Page 50)

Non-renewal of Agreement (§ 486.311) and De-certification (§ 486.312)

CMS is finalizing § 486.311 with modifications to paragraphs (a)(1) and (b) clarify that the non-renewal of an agreement after loss of a competition is limited to the OPO's agreement for designation to a DSA, rather than a nonrenewal of an agreement for certification. Additionally, CMS is finalizing § 486.312 as proposed with a minor wording change at § 486.312(b) to align with the corresponding requirement at § 486.314(a)(1). In the proposed rule, § 486.312(b) stated "Except in cases of urgent need, CMS gives written notice of the initial de-certification decision to an OPO at least 90 calendar days before the effective date of the de-certification." The corrected language in this final rule aligns with the title of § 486.314(a)(1) and is revised as follows: "Except in cases of urgent need, CMS provides an initial notice of de-certification to an OPO in writing at least 90 calendar days before the effective date of the de-certification." (Page 62)

Appeals (§ 486.314)

CMS proposed several changes to the appeals process. CMS proposed modifying the timeframes in the appeal process and converting all timeframes to calendar days. CMS proposed to codify a process for discretionary review by the CMS Administrator and clarify the appeal process for OPOs that are de-certified based on urgent need. Additionally, CMS proposed to allow an OPO to appeal the removal of a designation to a tier 3 DSA without de-certification for situations where an OPO has another DSA that is assigned to performance tier 1 or 2 in the final assessment period for re-certification. These changes would make sure that OPOs have timely appeal rights for any adverse determinations regarding an OPO's compliance with outcome measure standards in a particular DSA.

CMS is finalizing changes to § 486.314 as proposed. However, CMS is modifying § 486.314(p) to reflect a revision to § 486.308(a)(4) which has been revised to indicate that CMS would only select a single successor OPO for designation to the DSA when there is insufficient time to conduct a competition. (Page 72)

Re-certification and Competition (§ 486.316)

CMS is finalizing the proposed changes to § 486.316 with a modification at § 486.316(a)(2) to address the impact of outcome measures to OPO designation when an OPO is assigned a new DSA by CMS. CMS is clarifying that when DSAs are assigned by CMS under the provisions at § 486.308(a)(4) or § 486.316(e), CMS will not open any tier 2 DSA managed by that OPO for competition until a full 4-year recertification cycle is completed for the newly assigned DSA. CMS is also clarifying the language at § 486.316(b)(1) regarding the notice to the OPO. It is being revised from "initial de-certification determination" to an "initial notice of de-certification" as specified at § 486.314(a)(1). Additionally, CMS is revising § 486.316(c)(2) to clarify that a competition loss would result in non-renewal of the agreement for designation to a DSA. (Page 84)

Outcome Measures (§ 486.318)

CMS is finalizing the changes to § 486.318 as proposed. (Page 88)

Human Resources (§ 486.326)

CMS proposed to revise the medical director requirement to specify that an OPO's medical director would be required to be a physician licensed in at least one of the States or territories within one of the OPO's service areas or as required by State or territory law or by the jurisdiction in which the OPO is located.

CMS is finalizing the medical director requirement at § 486.326(d) as proposed. However, CMS is not finalizing the proposed licensure requirement at § 486.326(e) at this time. CMS says it may consider comments from the licensure proposal in future rulemaking. (Page 92)

IV. Comment Solicitation and Discussion on Emerging Issues (Page 101)

V. Collection Of Information Requirements (Page 106)

Comment

Note; there is no number VI.

VII. Regulatory Impact Analysis (Page 112)

Final Thoughts

Please note, not all subjects in the rule have been reflected in this analysis.