

# Hospital Waiver Request to Work with an OPO other than its Designated OPO

[Section 1138\(a\)\(1\)\(C\)](#) of the Social Security Act (the Act) requires that every hospital or critical access hospital (CAH) participating in Medicare have an agreement for organ procurement services only with its designated organ procurement organization (OPO). However, [section 1138\(a\)\(2\)](#) of the Act and [42 CFR 486.308\(e\)](#) provide that a hospital or CAH may request a waiver to have an agreement with an OPO other than the one designated by CMS. Such a request shall be granted if CMS determines that the hospital or CAH meets the following conditions, also described in [section 1138\(a\)\(2\)\(A\)](#) of the Act and [42 CFR 486.308\(e\)](#):

- the waiver is expected to increase organ donation, and
- the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital or CAH's designated OPO and within the service area served by the OPO with which the hospital or CAH seeks to enter into an agreement should the waiver be granted.

In making a determination on a waiver request, CMS also considers the following factors, described in [section 1138\(a\)\(2\)\(B\)](#) and [42 CFR 486.308\(f\)](#):

- cost effectiveness;
- improvements in quality;
- whether there has been any change in a hospital's designated OPO due to a change made on or after December 28, 1992, in the definitions for metropolitan statistical areas (as established by the Office of Management and Budget); and
- the length and continuity of a hospital's relationship with an OPO other than the hospital or CAH's designated OPO.

## Instructions for Submitting a Waiver Request

Waiver requests must be submitted electronically to [\*\*OPOWaiverRequests@cms.hhs.gov\*\*](mailto:OPOWaiverRequests@cms.hhs.gov). When the hospital or CAH submits a waiver request to this email address, CMS will send a response email acknowledging receipt of the submission.

A complete waiver request should include:

- Hospital or CAH's point of contact name, address, email and phone number.
- Hospital or CAH's CMS Certification Number (CCN).
- Hospital or CAH's legal business name and address.
- Data that establishes that the waiver is expected to increase organ donations and that the waiver will ensure equitable treatment of patients listed for transplants within the

service area served by the hospital or CAH's designated OPO and within the service area served by the OPO with which the hospital or CAH seeks to enter into an agreement.

- Any other information the hospital or CAH believes is relevant to its request.

### **Waiver Review Process**

CMS will post a notice in the Federal Register within 30 days of receiving the waiver application and offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date in the Federal Register.

Upon completion of CMS' review of the waiver application and the public comments, CMS will notify the hospital of its decision and simultaneously notify the OPOs that are affected by the waiver decision.

### **Questions**

Questions about the OPO waiver process can be submitted to [OPOWaiverRequests@cms.hhs.gov](mailto:OPOWaiverRequests@cms.hhs.gov).