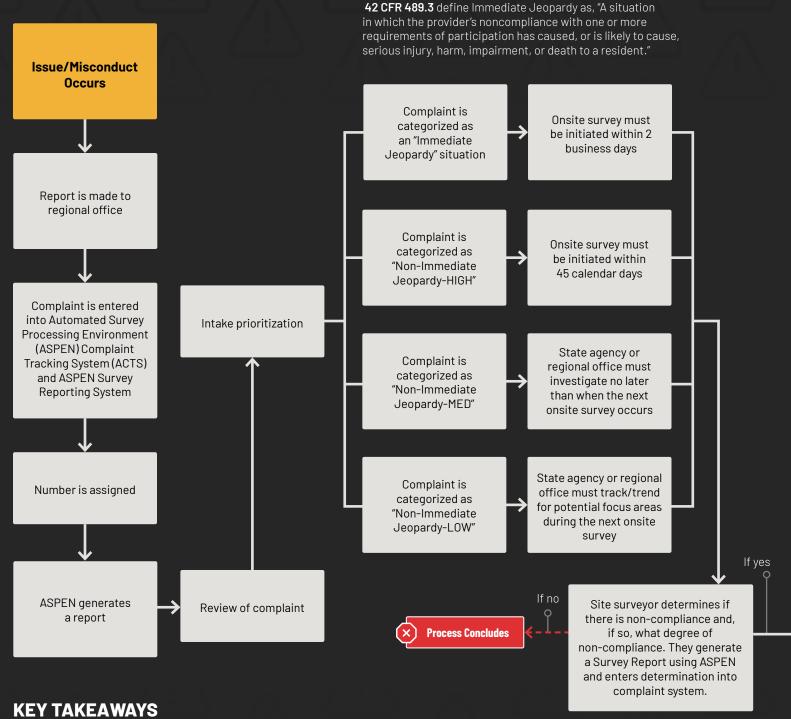
CMS Complaint Process



"I don't know how they would lodge a complaint...Sometimes the best way to file a complaint is to go to the news media."

- HHS Official

Process Concludes The choice to withdraw formally (via a written notice) stops the decertification process. A withdrawal or merger does not require public notice, while a decertification would. CMS approves or sets a different date OPO must send CMS written notice of its intention to terminate **Process Concludes** its agreement and the proposed effective date If surveyor determines OPO implemented corrective action At any point during and is now in termination process, OPO compliance has option to voluntarily withdraw (close or merge with another OPO) without penalty Site surveyor revisits to verify corrective action plan has been implemented Starts termination process: CMS mails notice to OPO of de-certification determination OPO submits corrective action plan If surveyor determines OPO has not implemented corrective action

If there is insufficient time before expiration of an agreement with CMS to allow for competition of the service area, CMS may choose to extend the OPO's agreement to allow for other OPOs to compete.

Public Notice is issued. OPO is no longer reimbursed by CMS for organ procurement services on or after the effective date of de-certification. CMS will then open the decertified OPO's service area for competition.

happened with an OPO

De-certification

is upheld

OPO is de-certified and it has no further administrative appeal rights.

Hearing officer renders a decision within 20 business days of the hearing

Hearing officer sets a

hearing date that is no

more than 60 calendar

days from receipt of

hearing request

New OPO is awarded the

donation service area

Reversal of de-certification Q determination

Process Concludes

The whole appeal Oprocess could take over 100 business days, or 5 months

OPO can request

reconsideration within

15 business days

If dissatisfied with decision, OPO must file a request for a hearing within 40 business days

Affirmation of de-certification determination

CMS makes a written reconsidered determination within 10 business days - affirming, reversing, or modifying the initial determination

> CMS surveyors are not specialized in the organ donation system, and so may miss problems and issues within an OPO's operation.

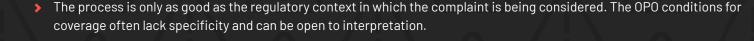
and is still in non-compliance

> There is a disconnect between CMS and HRSA, which have parallel but fractured oversight of OPOs - leading to things falling through the cracks and a diffusion of responsibility for various aspects of OPO and OPTN oversight.

Reversal of → de-certification determination **Process Concludes**







> Complaints are often not made because people are unaware of how to start the complaint process, have no faith that

OPO's fault is less visible compared to a transplant center.

auditing of these complaints.

filing a complaint will lead to any meaningful change (since no OPO has been successfully decertified), or because the

A patient's family might complain to the OPO directly but not know to bring the complaint to CMS, and there is no external



