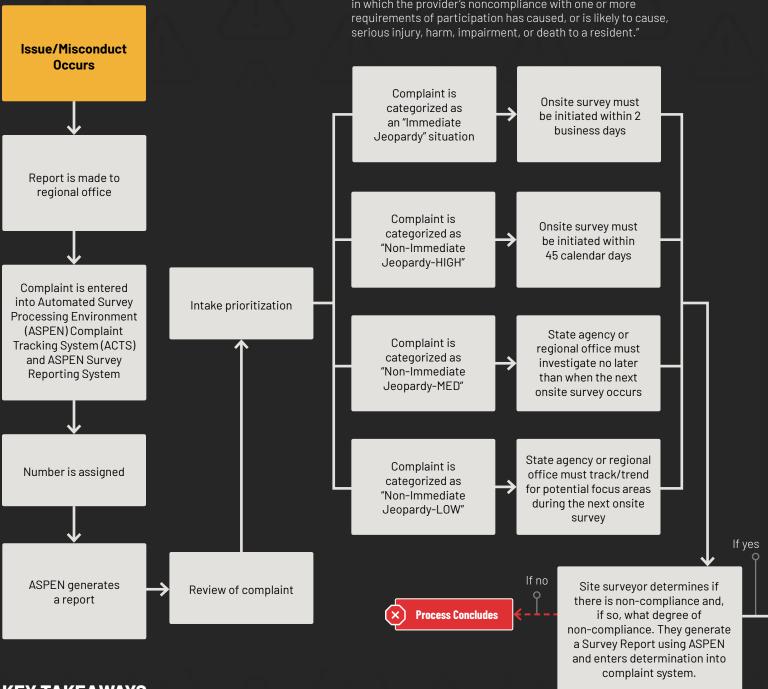
CMS Complaint Process



42 CFR 489.3 define Immediate Jeopardy as, "A situation in which the provider's noncompliance with one or more

(via a written notice) stops the decertification process. A withdrawal or merger does not require public notice, while a decertification would.

Process Concludes

If surveyor

determines OPO

corrective action

implemented

and is now in

compliance

Site surveyor revisits

to verify corrective

action plan has been

implemented

OPO submits corrective

action plan

The choice to withdraw formally

- HHS Official

CMS approves or sets a different date

"I don't know how they would

is to go to the news media."

lodge a complaint...Sometimes

the best way to file a complaint

OPO must send CMS written notice of its intention to terminate its agreement and the proposed effective date

Process Concludes

At any point during termination process, OPO has option to voluntarily withdraw (close or merge with another OPO) without penalty

> Starts termination process: CMS mails notice to OPO of de-certification determination

If surveyor determines OPO has not implemented corrective action and is still in non-compliance

New OPO is awarded the donation service area

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

Reversal of de-certification Q determination

Process Concludes

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

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

de-certification determination

Affirmation of

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.
- > 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**





OPO can request

reconsideration within

15 business days





KEY TAKEAWAYS

- > Complaints are often not made because people are unaware of how to start the complaint process, have no faith that filing a complaint will lead to any meaningful change (since no OPO has been successfully decertified), or because the OPO's fault is less visible compared to a transplant center.
- A patient's family might complain to the OPO directly but not know to bring the complaint to CMS, and there is no external auditing of these complaints.
- > The process is only as good as the regulatory context in which the complaint is being considered. The OPO conditions for coverage often lack specificity and can be open to interpretation.