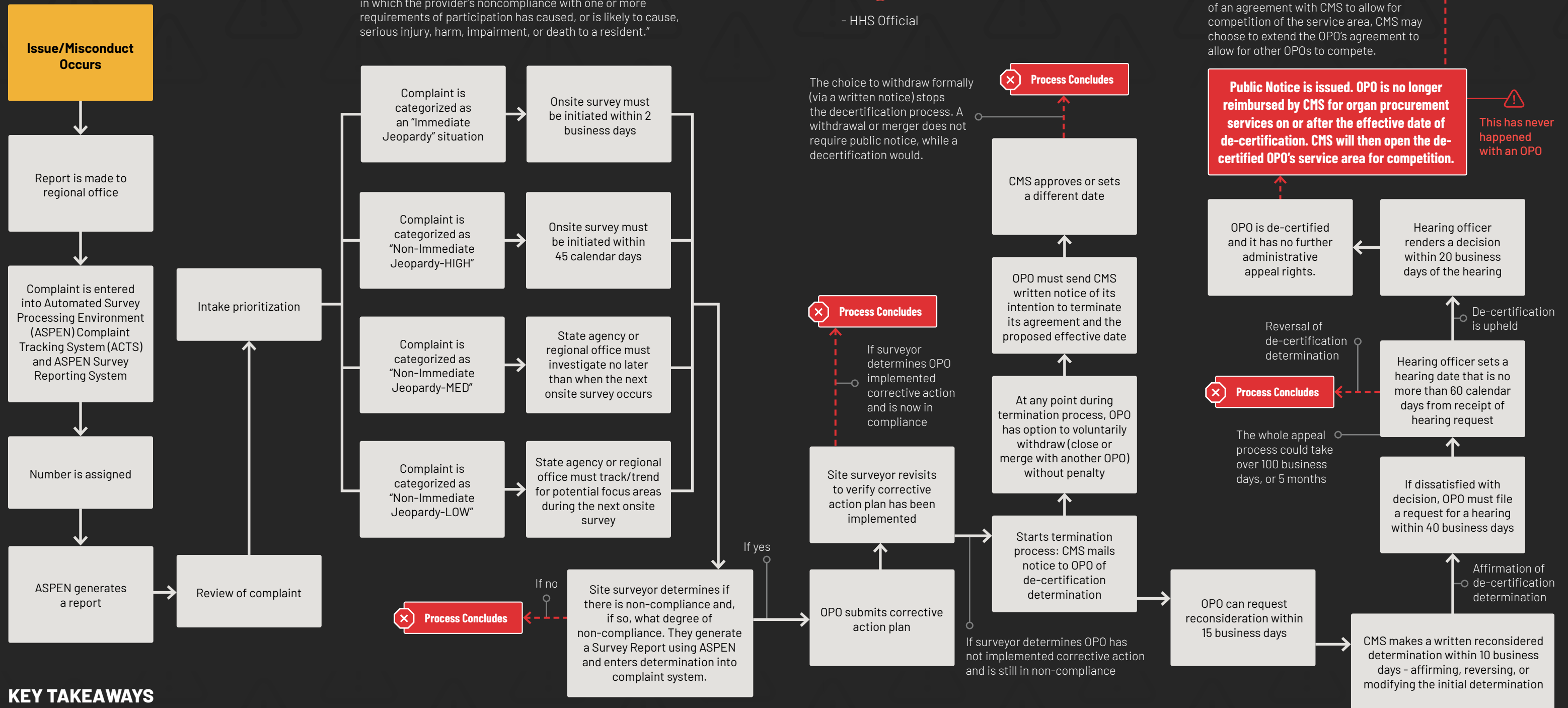


CMS Complaint Process

42 CFR 489.3 define Immediate Jeopardy as, "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."



“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

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.

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.

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.

- 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.