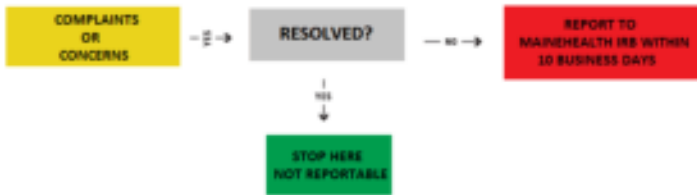


COMPLAINTS/CONCERNS



OTHER REPORTABLE INFORMATION



UNANTICIPATED PROBLEM (UP) / SERIOUS ADVERSE EVENT (SAE)

