- (2) THE ADMINISTRATION SHALL SEEK INPUT FROM INDIVIDUALS WITH DISABILITIES AND THEIR FAMILIES, LICENSEES, AND ADVOCACY ORGANIZATIONS IN DEVELOPING THE REGULATIONS, PRIOR TO PUBLISHING THE REGULATIONS IN THE MARYLAND REGISTER FOR PUBLIC COMMENT.
 - (3) THE REGULATIONS SHALL DEFINE AND ADDRESS:
- (I) THE PROCEDURES AND TIMELINES THAT PROVIDERS MUST FOLLOW WHEN REPORTING SERIOUS REPORTABLE INCIDENTS AND DEATHS TO THE ADMINISTRATION AND THE OFFICE OF HEALTH CARE QUALITY;
- (I) (II) THE SYSTEM OF PRIORITIZATION FOR INVESTIGATION OF SERIOUS REPORTABLE INCIDENTS AND DEATHS; THE DEPARTMENT'S PROTOCOL TO DETERMINE THE NECESSITY TO INVESTIGATE A SERIOUS REPORTABLE INCIDENT THAT TAKES INTO ACCOUNT:
 - 1. THE SEVERITY OF THE INCIDENT;
- 2. THE QUALITY OF THE LICENSEE'S INTERNAL INVESTIGATION; AND
- 3. THE NUMBER AND FREQUENCY OF SERIOUS REPORTABLE INCIDENTS REPORTED BY THE LICENSEE TO THE DEPARTMENT;
- (III) THE SPECIFIC ROLES AND RESPONSIBILITIES OF EACH GOVERNMENTAL UNIT INVOLVED IN INVESTIGATING LICENSEES ANY FOLLOW-UP INVESTIGATIONS THAT MAY OCCUR DUE TO A LICENSEE'S REPORT OF A SERIOUS REPORTABLE INCIDENT OR DEATH;
- $\frac{(HH)}{(IV)}$ METHODS OF INVESTIGATIONS, INCLUDING ON–SITE INVESTIGATIONS;
- $\frac{(IV)}{V}$ TIME LINES FOR RESPONSE TO SERIOUS REPORTABLE INCIDENTS AND DEATHS AND INVESTIGATION OF SERIOUS REPORTABLE INCIDENTS AND DEATHS;
- $\frac{\langle V \rangle}{\langle VI \rangle}$ TIME LINES FOR ISSUING SPECIFIED REPORTS, INCLUDING CORRECTIVE ACTION PLANS, TO THE ADMINISTRATION, LICENSEE, MORTALITY REVIEW COMMITTEE, MEDICAID FRAUD UNIT, INDIVIDUALS RECEIVING SERVICES FROM THE LICENSEE INVOLVED IN THE INCIDENT AND THEIR GUARDIANS OR FAMILY MEMBERS, AND OTHERS; AND
- $\frac{(\text{VII})}{\text{FOLLOW-UP PROTOCOLS FOR THE OFFICE OF HEALTH CARE}} \\ \underline{\text{QUALITY AND THE ADMINISTRATION TO ENSURE THAT CORRECTIVE ACTION HAS}} \\ \\ \underline{\text{BEEN IMPLEMENTED BY THE LICENSEE}}.$
- (VI) FOLLOW-UP MONITORING REQUIREMENTS AND TIME LINES FOR THE OFFICE OF HEALTH CARE QUALITY AND THE ADMINISTRATION TO ENSURE THAT CORRECTIVE ACTION HAS BEEN IMPLEMENTED BY THE LICENSEE; AND