First Tier, Downstream, and Related Entities (FDR) and Downstream and Delegated Entities (DDE) requirements

Frequently Asked Questions

1. What are the Centers for Medicare & Medicaid Services (CMS) FDR/DDE requirements?

   a) The FDR/DDE has a process in place to confirm its employees, contractors, board members, or any shareholders (interest of 5% or more) that work directly or indirectly on any federal health care program do not appear in the List of Excluded Individuals/Entities as published by the Department of Health and Human Services Office of the Inspector General, nor in the List of Debarred Contractors as published by the General Services Administration.

   b) The FDR/DDE, its employees, board members, producers, and contractors that provide administrative services or health care services for or to Medicare Advantage or QHP program members, participate in fraud, waste, and abuse training and general compliance training.

   c) The FDR/DDE agrees to comply with Regence Group (Regence) conflict of interest policy or a conflict of interest policy developed by FDR/DDE that meets CMS requirements.

   d) The FDR/DDE agrees to comply with Regence’s Code of Business Conduct (COBC) and policies and procedures, or to adopt and comply with its own code of conduct, disciplinary standards, and policies and procedures that reflect a commitment to detecting, preventing, and correcting non-compliance with Government Programs requirements in the delivery of Government Programs services, including detecting, preventing, and correcting fraud, waste, and abuse.

   e) The FDR/DDE is required to publish disciplinary standards which include its expectation that employees ask compliance questions and report potential and actual instances of non-compliance with Government Programs requirements to Regence through its anonymous hotline or through other means. Disciplinary standards must also state that any violation of these standards will result in appropriate disciplinary action, up to and including termination of employment. They also must include a non-retaliation policy for good-faith reporting.

   f) The FDR/DDE will report compliance or FWA concerns and will publicize to its employees the methods for reporting potential and actual instances of fraud, waste, and abuse to Regence through its anonymous hotline or through other means. Federal law prohibits Regence from retaliating against FDRs/DDEs or their employees for reporting a fraud, waste, and abuse issue.
2. What actions do FDRs/DDEs need to perform to be in compliance with the FDR/DDE requirements?

a) FDRs/DDEs will check the federal exclusion lists prior to hire and monthly thereafter.

b) If an employee, contractor, board member or shareholder (interest of 5% or more) is on either exclusion list, the FDR/DDE shall immediately remove the person or entity from any work related directly or indirectly to all federal health care programs and will take appropriate corrective actions, including preventing payment to excluded entity. The FDR/DDE will notify Regence of the finding and action.

c) Fraud, waste, and abuse training and general compliance training will be conducted within ninety (90) days of hire and annually thereafter and there will be documentation attesting to the completion of this annually.

d) The FDR/DDE will contact the Medicare and Ethics & Compliance hotlines with compliance questions and to report potential and actual instances of non-compliance.

e) Standards of Conduct and policies and procedures will be distributed to all employees who provide administrative services or health care services for Regence’s Medicare Advantage and QHP programs at time of hire and annually thereafter.

f) Conflict of interest disclosure forms will be distributed at time of hire and annually thereafter to governing body, officers and senior leadership, as applicable, certifying that they are free from any conflict of interest related to Federal programs.

g) Disciplinary standards must be publicized and include:
   a) Requirement to ask compliance questions and report potential and actual instances of noncompliance and FWA
   b) Violation of standards will result in appropriate disciplinary action up to and including termination
   c) Non-retaliation policy

h) If applicable, FDR/DDE shall ensure that payments are not made to any individual or entity included on the preclusion list.

3. Where will the FDR/DDE find tools related to meeting the CMS requirements?

a) Regence’s FDR/DDE web page: www.regence.com/fdr-resources

b) Details about how to report potential and actual instances of fraud, waste, and abuse may be found at https://www.regence.com/medicare/fraud

4. Are FDRs/DDEs required to use Regence’s compliance program to meet the requirements?

No. FDRs/DDEs may use a compliance program that meets CMS requirements, as long as documentation is maintained.
6. Can FDRs/DDEs develop and use their own general compliance and fraud, waste, and abuse training?

Yes. We recommend visiting CMS’ site to ensure current training topics are incorporated into your training.

7. What records do FDRs/DDEs need to keep and how will FDRs/DDEs be audited for compliance?

   a) The FDR/DDE will keep a record that confirms reviews of the two federal exclusion lists have been completed. This generally includes a copy of each exclusion list with confirmations for initial hires and monthly verifications thereafter, along with employee names and verification dates.

   b) A copy of fraud, waste, and abuse training and general compliance training materials will be maintained and proof that such training has been completed by its employees, board members, producers, and contractors (e.g. attestations).

   c) Copies of conflict of interest certifications for governing body, officers, and senior leadership, as applicable, directly or indirectly with the Federal health care program will be maintained and made available for audit purposes.

   d) Copies of Standards of Conduct attestations will be maintained and made available for audit purposes.

   e) Copies of compliance program policies and procedures, including non-retaliation policy and disciplinary standards will be reviewed.

8. How will FDRs/DDEs be monitored for compliance?

   FDRs/DDEs may be asked to provide documentation that demonstrates compliance with the FDR/DDE requirements.