

agents or employers that violate its regulations.

§ 40.363 On what basis may the Department issue a PIE?

(a) If you are a service agent, the Department may issue a PIE concerning you if we determine that you have failed or refused to provide drug or alcohol testing services consistent with the requirements of this part or a DOT agency drug and alcohol regulation.

(b) The Department also may issue a PIE if you have failed to cooperate with DOT agency representatives concerning inspections, complaint investigations, compliance and enforcement reviews, or requests for documents and other information about compliance with this part or DOT agency drug and alcohol regulations.

§ 40.365 What is the Department's policy concerning starting a PIE proceeding?

(a) It is the Department's policy to start a PIE proceeding only in cases of serious, uncorrected noncompliance with the provisions of this part, affecting such matters as safety, the outcomes of test results, privacy and confidentiality, due process and fairness for employees, the honesty and integrity of the testing program, and cooperation with or provision of information to DOT agency representatives.

(b) The following are examples of the kinds of serious noncompliance that, as a matter of policy, the Department views as appropriate grounds for starting a PIE proceeding. These examples are not intended to be an exhaustive or exclusive list of the grounds for starting a PIE proceeding. We intend them to illustrate the level of seriousness that the Department believes supports starting a PIE proceeding. The examples follow:

(1) For an MRO, verifying tests positive without interviewing the employees as required by this part or providing MRO services without meeting the qualifications for an MRO required by this part;

(2) For a laboratory, refusing to provide information to the Department, an employer, or an employee as required by this part; failing or refusing to conduct a validity testing program

when required by this part; or a pattern or practice of testing errors that result in the cancellation of tests. (As a general matter of policy, the Department does not intend to initiate a PIE proceeding concerning a laboratory with respect to matters on which HHS initiates certification actions under its laboratory guidelines.);

(3) For a collector, a pattern or practice of directly observing collections when doing so is unauthorized, or failing or refusing to directly observe collections when doing so is mandatory;

(4) For collectors, BATs, or STTs, a pattern or practice of using forms, testing equipment, or collection kits that do not meet the standards in this part;

(5) For a collector, BAT, or STT, a pattern or practice of "fatal flaws" or other significant uncorrected errors in the collection process;

(6) For a laboratory, MRO or C/TPA, failing or refusing to report tests results as required by this part or DOT agency regulations;

(7) For a laboratory, falsifying, concealing, or destroying documentation concerning any part of the drug testing process, including, but not limited to, documents in a "litigation package";

(8) For SAPs, providing SAP services while not meeting SAP qualifications required by this part or performing evaluations without face-to-face interviews;

(9) For any service agent, maintaining a relationship with another party that constitutes a conflict of interest under this part (*e.g.*, a laboratory that derives a financial benefit from having an employer use a specific MRO);

(10) For any service agent, representing falsely that the service agent or its activities is approved or certified by the Department or a DOT agency;

(11) For any service agent, disclosing an employee's test result information to any party this part or a DOT agency regulation does not authorize, including by obtaining a "blanket" consent from employees or by creating a data base from which employers or others can retrieve an employee's DOT test results without the specific consent of the employee;

(12) For any service agent, interfering or attempting to interfere with

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the ability of an MRO to communicate with the Department, or retaliating against an MRO for communicating with the Department;

(13) For any service agent, directing or recommending that an employer fail or refuse to implement any provision of this part; or

(14) With respect to noncompliance with a DOT agency regulation, conduct that affects important provisions of Department-wide concern (*e.g.*, failure to properly conduct the selection process for random testing).

§ 40.367 Who initiates a PIE proceeding?

The following DOT officials may initiate a PIE proceeding:

(a) The drug and alcohol program manager of a DOT agency;

(b) An official of ODAPC, other than the Director; or

(c) The designee of any of these officials.

§ 40.369 What is the discretion of an initiating official in starting a PIE proceeding?

(a) Initiating officials have broad discretion in deciding whether to start a PIE proceeding.

(b) In exercising this discretion, the initiating official must consider the Department's policy regarding the seriousness of the service agent's conduct (see § 40.365) and all information he or she has obtained to this point concerning the facts of the case. The initiating official may also consider the availability of the resources needed to pursue a PIE proceeding.

(c) A decision not to initiate a PIE proceeding does not necessarily mean that the Department regards a service agent as being in compliance or that the Department may not use other applicable remedies in a situation of non-compliance.

§ 40.371 On what information does an initiating official rely in deciding whether to start a PIE proceeding?

(a) An initiating official may rely on credible information from any source as the basis for starting a PIE proceeding.

(b) Before sending a correction notice (see § 40.373), the initiating official informally contacts the service agent to

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determine if there is any information that may affect the initiating official's determination about whether it is necessary to send a correction notice. The initiating official may take any information resulting from this contact into account in determining whether to proceed under this subpart.

§ 40.373 Before starting a PIE proceeding, does the initiating official give the service agent an opportunity to correct problems?

(a) If you are a service agent, the initiating official must send you a correction notice before starting a PIE proceeding.

(b) The correction notice identifies the specific areas in which you must come into compliance in order to avoid being subject to a PIE proceeding.

(c) If you make and document changes needed to come into compliance in the areas listed in the correction notice to the satisfaction of the initiating official within 60 days of the date you receive the notice, the initiating official does not start a PIE proceeding. The initiating official may conduct appropriate fact finding to verify that you have made and maintained satisfactory corrections. When he or she is satisfied that you are in compliance, the initiating official sends you a notice that the matter is concluded.

§ 40.375 How does the initiating official start a PIE proceeding?

(a) As a service agent, if your compliance matter is not correctable (see § 40.373(a)), or if have not resolved compliance matters as provided in § 40.373(c), the initiating official starts a PIE proceeding by sending you a notice of proposed exclusion (NOPE). The NOPE contains the initiating official's recommendations concerning the issuance of a PIE, but it is not a decision by the Department to issue a PIE.

(b) The NOPE includes the following information:

(1) A statement that the initiating official is recommending that the Department issue a PIE concerning you;

(2) The factual basis for the initiating official's belief that you are not providing drug and/or alcohol testing services to DOT-regulated employers