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whether your principals tolerated their noncompliance; and

(3) Whether you had effective standards of conduct and control systems (both with respect to your own organization and any contractors or affiliates) at the time the noncompliance occurred;

(e) Whether you have demonstrated an appropriate compliance disposition, including such factors as the following:

(1) Whether you have accepted responsibility for the noncompliance and recognize the seriousness of the conduct that led to the cause for issuance of the PIE;

(2) Whether you have cooperated fully with the Department during the investigation. The Director may consider when the cooperation began and whether you disclosed all pertinent information known to you;

(3) Whether you have fully investigated the circumstances of the noncompliance forming the basis for the PIE and, if so, have made the result of the investigation available to the Director;

(4) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity that constitutes the grounds for issuance of the PIE; and

(5) Whether your organization has taken appropriate corrective actions or remedial measures, including implementing actions to prevent recurrence;

(f) With respect to noncompliance with a DOT agency regulation, the degree to which the noncompliance affects matters common to the DOT drug and alcohol testing program;

(g) Other factors appropriate to the circumstances of the case.

§40.391 What is the scope of a PIE?

(a) The scope of a PIE is the Department's determination about the divisions, organizational elements, types of services, affiliates, and/or individuals (including direct employees of a service agent and its contractors) to which a PIE applies.

(b) If, as a service agent, the Department issues a PIE concerning you, the PIE applies to all your divisions, organizational elements, and types of services that are involved with or affected by the noncompliance that forms the factual basis for issuing the PIE.

(c) In the NOPE (see §40.375(b)(4)), the initiating official sets forth his or her recommendation for the scope of the PIE. The proposed scope of the PIE is one of the elements of the proceeding that the service agent may contest (see §40.381(b)) and about which the Director makes a decision (see §40.387(b)(3)).

(d) In recommending and deciding the scope of the PIE, the initiating official and Director, respectively, must take into account the provisions of paragraphs (e) through (j) of this section.

(e) The pervasiveness of the noncompliance within a service agent's organization (see §40.389(d)) is an important consideration in determining the scope of a PIE. The appropriate scope of a PIE grows broader as the pervasiveness of the noncompliance increases.

(f) The application of a PIE is not limited to the specific location or employer at which the conduct that forms the factual basis for issuing the PIE was discovered.

(g) A PIE applies to your affiliates, if the affiliate is involved with or affected by the conduct that forms the factual basis for issuing the PIE.

(h) A PIE applies to individuals who are officers, employees, directors, shareholders, partners, or other individuals associated with your organization in the following circumstances:

(1) Conduct forming any part of the factual basis of the PIE occurred in connection with the individual's performance of duties by or on behalf of your organization; or

(2) The individual knew of, had reason to know of, approved, or acquiesced in such conduct. The individual's acceptance of benefits derived from such conduct is evidence of such knowledge, acquiescence, or approval.

(i) If a contractor to your organization is solely responsible for the conduct that forms the factual basis for a PIE, the PIE does not apply to the service agent itself unless the service agent knew or should have known about the conduct and did not take action to correct it.

(j) PIEs do not apply to drug and alcohol testing that DOT does not regulate.

(k) The following examples illustrate how the Department intends the provisions of this section to work:

Example 1 to § 40.391. Service Agent P provides a variety of drug testing services. P's SAP services are involved in a serious violation of this Part 40. However, P's other services fully comply with this part, and P's overall management did not plan or concur in the noncompliance, which in fact was contrary to P's articulated standards. Because the noncompliance was isolated in one area of the organization's activities, and did not pervade the entire organization, the scope of the PIE could be limited to SAP services.

Example 2 to § 40.391. Service Agent Q provides a similar variety of services. The conduct forming the factual basis for a PIE concerns collections for a transit authority. As in Example 1, the noncompliance is not pervasive throughout Q's organization. The PIE would apply to collections at all locations served by Q, not just the particular transit authority or not just in the state in which the transit authority is located.

Example 3 to § 40.391. Service Agent R provides a similar array of services. One or more of the following problems exists: R's activities in several areas—collections, MROs, SAPs, protecting the confidentiality of information—are involved in serious noncompliance; DOT determines that R's management knew or should have known about serious noncompliance in one or more areas, but management did not take timely corrective action; or, in response to an inquiry from DOT personnel, R's management refuses to provide information about its operations. In each of these three cases, the scope of the PIE would include all aspects of R's services.

Example 4 to § 40.391. Service Agent W provides only one kind of service (*e.g.*, laboratory or MRO services). The Department issues a PIE concerning these services. Because W only provides this one kind of service, the PIE necessarily applies to all its operations.

Example 5 to § 40.391. Service Agent X, by exercising reasonably prudent oversight of its collection contractor, should have known that the contractor was making numerous ''fatal flaws'' in tests. Alternatively, X received a correction notice pointing out these problems in its contractor's collections. In neither case did X take action to correct the problem. X, as well as the contractor, would be subject to a PIE with respect to collections.

Example 6 to § 40.391. Service Agent Y could not reasonably have known that one of its MROs was regularly failing to interview employees before verifying tests positive. When it received a correction notice, Y immediately dismissed the erring MRO. In this case, the MRO would be subject to a PIE but Y would not.

Example 7 to § 40.391. The Department issues a PIE with respect to Service Agent Z. Z provides services for DOT-regulated transportation employers, a Federal agency under the HHS-regulated Federal employee testing program, and various private businesses and public agencies that DOT does not regulate. The PIE applies only to the DOT-regulated transportation employers with respect to their DOT-mandated testing, not to the Federal agency or the other public agencies and private businesses. The PIE does not prevent the non-DOT regulated entities from continuing to use Z's services.

§ 40.393 How long does a PIE stay in effect?

(a) In the NOPE (see § 40.375(b)(5)), the initiating official proposes the duration of the PIE. The duration of the PIE is one of the elements of the proceeding that the service agent may contest (see § 40.381(b)) and about which the Director makes a decision (see § 40.387(b)(4)).

(b) In deciding upon the duration of the PIE, the Director considers the seriousness of the conduct on which the PIE is based and the continued need to protect employers and employees from the service agent's noncompliance. The Director considers factors such as those listed in § 40.389 in making this decision.

(c) The duration of a PIE will be between one and five years, unless the Director reduces its duration under § 40.407.

§ 40.395 Can you settle a PIE proceeding?

At any time before the Director's decision, you and the initiating official can, with the Director's concurrence, settle a PIE proceeding.

§ 40.397 When does the Director make a PIE decision?

The Director makes his or her decision within 60 days of the date when the record of a PIE proceeding is complete (including any meeting with the Director and any additional fact-finding that is necessary). The Director may extend this period for good cause for additional periods of up to 30 days.