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*Via electronic submission to IG_Rules_Comments_Inbox@hhsc.state.tx.us*

Jim Harrison
Government Relations
Inspector General – Health and Human Services Commission
11501 Burnet Rd., Building 902
Austin, TX 78758

**PUBLIC COMMENT LETTER**

Re: Comments on Criteria the Office of Investigator General of the Texas Health and Human Services Commission Uses to Determine Administrative Actions or Sanctions For Provider Violations, 1 Tex. Admin. Code §§ 371.1603(f)-371.1603(h) and 1 Tex. Admin. Code § 371.1715

Dear Mr. Harrison:

On behalf of our more than 465 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association appreciates the opportunity to provide comments on the above-referenced rules regarding the criteria HHSC-OIG uses to determine administrative actions or sanctions for provider violations. In general, THA believes that the OIG should determine administrative actions and sanctions based on an individualized inquiry of the person; the person's conduct before, during, and after an alleged violation; the financial or other harm; and the pervasiveness of the improper conduct within the organization. THA respectfully offers the following comments. Unless otherwise specified, all legal citations refer to Title 1 of the Texas Administrative Code.

## I. Proposed Changes 1 Tex. Admin. Code § 371.1603(f)

THA suggests the following changes to 1 Tex. Admin. Code § 371.1603(f), which are explained below.

(f) In determining the appropriate administrative action or sanction, including the amount of any administrative penalty to assess, the OIG considers:
(1) the seriousness of the violation;
(2) the prevalence of errors by the provider;
(3) the financial or other harm to the state or recipients, in proportion to the size of the entity;
(4) the amount necessary to deter future violations;
(5) actions by the provider to correct the problem;
(6) the cost of enforcement; and
~~(4)~~(7) any aggravating or mitigating factors the OIG determines appropriate.

Section 371.1603(f)(3) of the Texas Administrative Code should be revised to specify that the financial or other harm resulting from an entity's actions should be viewed in proportion to the size of the entity. The approach is good policy because the amount of the financial harm caused is highly dependent on the amount of reimbursement that is regularly received by the provider. Thus, a minor administrative mistake committed by a large provider should not be treated more severely than a fraud committed by a sole practitioner just because the practitioner's fraud causes less financial harm.

Similar to the previous comment, the OIG should consider the type and amount of any penalty in relation to deterrence. This amount will vary depending on the nature and extent of the violation as well as the size of the defendant. THA suggests adding a new § 371.1603(f)(4) requiring the OIG to consider the "the amount necessary to deter future violations . . . ."

THA also proposes to require the OIG to consider "actions by the provider to correct the problem" in § 371.1603(f)(5), rather than solely as a mitigating factor, because the OIG must consider the factors in § 371.1603(f), but has discretion about whether to consider aggravating and mitigating factors in §§ 371.1603(g) and 371.1603(h), as well as discretion to pick which aggravating or mitigating factors to consider. Corrective action by a provider should always be relevant to a punishment, and it is good public policy to encourage this behavior.

**II. Proposed Changes to 1 Tex. Admin. Code § 371.1603(g)**

Section 371.1603(g) describes the aggravating factors OIG may consider. THA suggests the following changes to § 371.1603(g), which are detailed below.

> (g) The following may be considered as aggravating factors that warrant more severe or restrictive action by the OIG. The OIG shall have the burden to identify evidence regarding any aggravating factors that may apply in the particular case. Aggravating factors may include:
> (1) harm to ~~one or~~ more than one patient~~s~~;
> (2) the nature and severity of patient harm;
> (3) one or more violations that involve more than one patient;
> (4) economic harm to any individual or entity and the severity of such harm;
> (5) the involvement of multiple or supervisory individuals indicating a systemic problem in an organization;
> ~~(5)~~(6) increased potential for harm to the public;
> ~~(6)~~(7) attempted concealment of the act constituting a violation;
> ~~(7)~~(8) intentional, premeditated, knowing, or grossly negligent act constituting a violation;
> ~~(8)~~(9) prior similar violations;
> ~~(9)~~(10) previous disciplinary action by a licensing board, any government agency, peer review organization, or health care entity;
> ~~(10)~~(11) violation of a licensing board or government agency order; or
> ~~(11)~~(12) other relevant circumstances increasing the seriousness of the misconduct.

The OIG should be required to justify any aggravating circumstances, instead of having the ability to use broad discretion to increase punishment. This would mirror the provider's obligation to demonstrate mitigating factors.

*See* § 3711603(h). Section 371.1603(g) should include the following sentence: "The OIG shall have the burden to identify evidence regarding any aggravating factors that may apply in the particular case."

The OIG already considers harm to a recipient in § 371.1603(f)(4), so it should only be aggravating if there is harm to more than one patient. THA suggest the following revision to § 371.1603(g)(1): "harm to ~~one or~~ more than one patient~~s~~." This would be a technical change.

Considering not just the severity, but also the nature of patient harm is important because the harm could be physical or financial. THA proposes to revise § 371.1603(g)(2) to "the nature and severity of patient harm . . . ."

To account for systemic harm with multiple wrongdoers, a new § 371.1603(g)(6) should be added to make "the involvement of multiple or supervisory individuals indicating a systemic problem in an organization" an aggravating factor. Wrongdoing that is pervasive throughout an organization should be aggravating. Isolated activity should be mitigating.

**III. Proposed Changes to 1 Tex. Admin. Code § 371.1603(h)**

THA suggests the following changes to 1 Tex. Admin. Code § 371.1603(h):

> (h) The following may be considered as mitigating factors that warrant less severe or restrictive action by the OIG. The provider shall have the burden to present evidence regarding any mitigating factors that may apply in the particular case. Mitigating factors may include:
> (1) self-reported and voluntary admissions of violation(s);
> (2) extent of the provider's investigation;
> (3) the involvement of few or only one individual(s) in an organization;
> ~~(2)~~(4) implementation of remedial measures to correct or mitigate harm from the violation(s)~~;~~, including recognition of the investment of resources;
> ~~(3)~~ (5) ~~acknowledgment of wrongdoing and~~ willingness to cooperate with the OIG~~, as evidenced by acceptance of a settlement agreement~~;
> (6) prompt repayment of funds collected in error;
> ~~(4)~~(7) rehabilitative potential;
> ~~(5)~~(8) prior community service and present value to the community;
> (9) history of Medicaid program compliance;
> (10) disciplinary or other action taken by the provider against the individual(s) involved in the conduct;
> (11) changes to the entity following the violations, including, but not limited to, implementation of enhanced compliance efforts or change of ownership or control to an entity with a history of compliant participation in the Medicaid program;
> ~~(6)~~ (12) other relevant circumstances reducing the seriousness of the misconduct; or
> ~~(7)~~ (13) other relevant circumstances lessening responsibility for the misconduct.

A new § 371.1603(h)(2) should be added to consider "the extent of the provider's investigation" a mitigating factor. The OIG should encourage and reward internal investigation because it is a good practice for the public and because it preserves the resources of the OIG.

To complement THA's proposed change to § 371.1603(g)(6), the OIG should add a new § 371.1603(h)(3) that makes "the involvement of few or only one individual(s) in an organization" a mitigating factor. Actions by a rogue employee should be considered mitigating. Aggravation or mitigation should at least partially depend on the pervasiveness of wrongdoing in an organization.

The OIG should consider the provider's investment of resources to put remedial measures in place to be a mitigating factor in § 371.1603(h)(2) (moved to § 371.1603(h)(4) above). Concrete actions demonstrate intent to rectify and prevent harm done and also come with a significant cost – both in time and resources. The OIG should encourage and reward this behavior.

THA recommends revising § 371.1603(h)(3) to only consider only willingness to cooperate with the OIG and exclude both acknowledgment of wrongdoing and acceptance of a settlement agreement from this analysis. Section 371.1603(h)(3) would move to § 371.1603(h)(5) and would mitigate punishment based on the person's "~~acknowledgment of wrongdoing and~~ willingness to cooperate with the OIG~~, as evidenced by acceptance of a settlement agreement~~ . . . ." Conditioning leniency on acknowledgment of wrongdoing, where, for example, a provider makes an error or an employee in the provider's organization commits wrongdoing, does not provide the proper flexibility to the OIG. In addition, using acceptance of a settlement agreement as evidence of cooperation seemingly requires the end result of a settlement agreement as retroactive proof of mitigation. Cooperation should be based on meaningful help and participation by the provider as evidenced by the provider's entire course of conduct during the investigation.

THA recommends adding a new § 371.1603(h)(6) to make "prompt repayment of funds collected in error" a mitigating factor. The OIG should encourage prompt return of any overpayment or improper payment. Further, a commitment to quickly rectifying harm demonstrates responsible action by the provider.

Three related mitigating factors should be added to §§ 371.1603(h)(9)-371.1603(h)(11): history of compliance, a consideration of actions taken against those involved in the conduct, and changes to the person or entity. These mitigating factors are recognized in the OIG Criteria. An entity's history of compliance, including self disclosures made appropriately and in good faith to the OIG or HHSC, indicates that the entity proactively seeks to remain compliant and invests resources into its compliance activities. Such history of proactive compliance should be considered where the OIG pursues an action against the person or entity, especially in the event of a program violation that did not involve fraud or other intent to violate program requirements. Changes to the entity should be included as a mitigating factor as well. For example, if, since the end of the conduct at issue, the entity has been sold to another, unrelated entity with a history of compliant participation in Medicaid, the change in ownership should be considered by the OIG as a mitigating factor in taking action against the new owner if the new owner was not involved with the conduct and has otherwise remained compliant with applicable regulatory requirements. Other changes could include disciplinary actions against individuals responsible for the conduct (which THA proposes to add in § 371.1603(h)(10)) or a significant increase in the resources allocated to compliance (which THA proposes to add in § 371.1603(h)(4)). While the latter two examples would also constitute "remedial measures" under the current § 371.1603(h), significant remedial actions should be recognized as changes to the entity.

## IV. Proposed Changes to 1 Tex. Admin. Code § 371.1715

THA suggests the following changes to 1 Tex. Admin. Code § 371.1715(b):

> (b) When determining whether or not a person is prohibited from providing or arranging to provide health care services under the Medicaid program, the OIG considers the following:
> (1) the person's knowledge of the violation and whether the conduct was intentional;
> (2) the role of the person and the nature and extent of the person's participation in the activity or violation;
> (3) actions taken by the person to investigate, mitigate, and correct the violation and to prevent future violations;
> (4) the extent of the person's cooperation in the investigation;
> ~~(2)~~ (5) the likelihood that education provided to the person would be sufficient to prevent future violations;
> ~~(3)~~(6) the potential impact on availability of services in the community served by the person; and
> ~~(4)~~(7) any other reasonable factor identified by the OIG.

Given the implications of exclusion from the Medicaid program, the OIG should consider the actions taken by the individual subject to an enforcement action. Adding an inquiry into whether the conduct of the individual was intentional in § 371.1715(b)(1) suggests that purposeful participation in a wrongful act is more likely to subject an individual to exclusion. In addition, the OIG should consider the nature and extent of the individual's participation in the conduct resulting in a violation, which THA proposes to include in § 371.1715(b)(2). Investigation, prevention, and mitigation by an individual should result in ongoing participation in the program because these activities suggest that the individual is unlikely to repeat the conduct. THA proposes adding a new § 371.1715(b)(3) to require the OIG to look at factors indicating an individual's commitment to prevention and mitigation. Finally, the OIG should consider cooperation by an individual as a factor for exclusion. Again, cooperation is an activity that public policy should encourage. THA proposes adding an evaluation into the extent of a person's cooperation in an investigation in § 371.1715(b)(4).

## V. General Recommendation: Administrative Errors Should Be Subject to Recoupment Only

The OIG's regulations should also be amended to clarify that, where the conduct that results in an overpayment does not involve fraud, waste or abuse, the only action that would be taken is recoupment of the overpayment amount. An express policy of remedying administrative errors through recoupment would be fair and similar to the regulatory framework governing the Medicare program. Sections 371.1651-371.1669 enumerate the various conduct that can serve as a basis for administrative actions or sanctions by the OIG. While most of the conduct described in these provisions is the type of conduct that is commonly defined as fraud, waste or abuse, some of the described conduct includes administrative errors that are not fraud, waste or abuse. For example, under § 371.1653(3), the OIG has the authority to subject a person to administrative action or sanctions "if the person submits, or causes to be submitted, a claim for payment by the Medicaid or other HHS program . . . for an item or service that requires prior authorization . . . where prior authorization . . . was not properly obtained . . . ." In the rulemaking promulgating this provision, the OIG acknowledged that the provision applies to conduct that is not fraud, waste, and abuse, and that the conduct is listed in the regulations to ensure that the OIG has the authority to recoup the overpayments that are caused by "simple mistakes:"

> *The provision is expressly limited to those instances in which the particular item required prior authorization. There is no edit system in place to capture claims for payment when the provider failed to obtain prior authorization… HHSC's only recourse is to recoup the payment from the provider. OIG recaptures overpayments that may result from fraud, waste, abuse, or simple mistake. The fact that an event is listed as a program violation does not imply that the provider was committing fraudulent activity. But in order for OIG to seek recoupment of an overpayment, which is a sanction, the error must be prohibited by rule as a program violation.*

(emphasis added) 37 Tex. Reg. 7989, 7995 (Oct. 5, 2012).

While the OIG explains its reasoning for listing conduct that may lead to an overpayment, there should be additional demarcation in the regulations between actions addressing fraud, waste, and abuse, and actions that address simple mistakes. Currently, the OIG's regulations do not establish limits on the actions that can be taken in the case of a simple mistake, where no fraud, waste or abuse has been committed. The OIG's regulations should be amended to clarify that conduct that results in an overpayment but does not involve fraud, waste or abuse, should be subject to recoupment only. This approach would be fair, establishing that persons that do not commit any wrongdoing would not be subject to penalties beyond rectifying the overpayment. This approach would also be similar to the regulatory framework governing the Medicare program. Under the authorities governing the Medicare program, an overpayment that is the result of an administrative error is subject to recoupment only. Specifically, 42 C.F.R. § 405.371(a)(3) establishes that a Medicare contractor may offset or recoup payment against a provider or supplier if the Medicare contractor or the Centers for Medicare & Medicaid Services has determined that the provider or supplier has been overpaid. Separately, 42 C.F.R. § 405.371 addresses payment suspension in cases of suspected fraud, and the Civil Monetary Penalty statute addresses various fraud, waste, and abuse activities, such as employing excluded individuals and retaining a known overpayment (*see* 42 U.S.C. § 1320a-7a(a)). Thus, while a Medicare contractor has the authority to recoup an overpayment, the HHS OIG does not have authority to impose sanctions on a person based on that person's administrative error that is not fraud, waste or abuse. This should also be the regulatory framework for the OIG's actions against providers that participate in Texas Medicaid.

Thank you for your consideration of these comments. We look forward to working with you on these issues. Should you have any questions, please do not hesitate to contact me at cduncan@tha.org or 512/465-1539.

Respectfully submitted,

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