Physicians Caring for Texans

September 7, 2012

Ms. Lisa Barragan
Texas Health & Human Services Commission
P.O. Box 85200
MC H400
Austin, Texas 78708-5200

Re: 1 TAC 371, Subchapter G

Dear Ms. Barragan:

The Texas Medical Association (TMA) is a private, voluntary, nonprofit association of over 45,000 Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, our maxim continues in the same direction: "Physicians Caring for Texans." TMA's diverse physician members practice in all fields of medical specialization.

The Office of Inspector General has the duty and obligation to investigate allegations of fraud involving Medicaid and other Health and Human Services programs. Without question, TMA supports reasonable and fair program integrity initiatives designed to discover, prevent, and correct fraud, waste, and abuse. It is imperative that taxpayer supported programs operate efficiently and provide care at the right time and place to eligible enrollees.

TMA does oppose, however, the OIG exercising authority over Texas physicians without providing the physicians meaningful substantive rights and procedural due process. In that regard, TMA strongly opposes the proposed rules because they expand OIG's authority, minimize the rights of physicians and other providers, and have a tenor that implies a presumption of wrongdoing.

The OIG's current rule section 371.1603(f), proposed for repeal, states "not all actions resulting in overpayment to a provider are necessarily fraudulent." The current rule eliminates this language, setting a tone quite the opposite. We ask that this language be reinstated and that the OIG reiterate in the new rules that not all actions or overpayments are fraud, and some billing or program errors are just mistakes. Further, the

new rules omit fair language found in the federal regulations such as a list of good cause exceptions, thus underscoring the OIG's view that any error should be subject to significant sanctions.

TMA strenuously opposes many aspects of these proposed rules, which would significantly expand the scope of the OIG's authority if adopted. Although this letter lists many specific concerns, TMA has two very significant objections regarding the proposed rules: 1) The rules do not clearly define a reasonable standard and process for "verifying" a credible allegation of fraud prior to initiating a payment hold, and they unreasonably and unnecessarily expand the discretion of the OIG to initiate a payment hold; and 2) They define affiliate extremely broadly to allow payment holds and other sanctions and penalties to be imposed on a person based solely on the actions of another.

TMA offers the following specific comments to these proposed rules.

Section 371.1709 Payment Hold

These proposed rules would expand OIG authority in an almost unrestrained way, beyond even what has been authorized by federal or state law. In essence, the Texas OIG is proposing to exercise more governmental power and control over individuals than what was authorized by the Patient Protection and Affordable Care Act (PPACA).

PPACA authorizes suspension of Medicaid payments *pending investigation of credible allegations of fraud*, in its amendment to section 1903(i)(2) of the Social Security Act. The Centers for Medicare and Medicaid Services (CMS) has limited the definition of "credible allegation of fraud" in 42 CFR§ 455.2. A credible allegation of fraud, according to the CMS March 2011 Bulletin to States, means an allegation that has been *verified* by the state *and* has an indicia of reliability.[1] When OIG receives an allegation of fraud, it is required to do an integrity review "to determine whether there is sufficient basis to warrant a full investigation.[2] Once a State verifies an allegation of fraud, pursuant to a preliminary investigation, it is required to refer the suspected fraud to the Medicaid Fraud Control Unit (MFCU). The OIG is only authorized to suspend Medicaid payment *after* it *verifies* there is a credible allegation of fraud for which an investigation is pending at the MFCU. If the MFCU declines to accept referral, the state must immediately release the payment

[1] See CMS March 25, 2011 CPI-CMSC Informational Bulletin, Guidance to States.

[2] 42 CFR § 455.14 requires an agency to conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation. Texas Government Code section 531.102(f) requires the OIG to conduct an "integrity review" to determine whether there is sufficient basis to warrant a full investigation. 42 CFR 455.23 requires the State Medicaid agency to suspend all Medicaid payments after the agency determines there is a credible allegation of fraud "for which an investigation is pending."

suspension.[3] In fact, on a quarterly basis, the state must request a certification from the MFCU that any matter accepted on the basis of a referral "continues to be under investigation thus warranting continuation of the suspension."[4] Furthermore, the state may impose a partial payment suspension if it believes that there is good cause.[5]

These OIG proposed rules, however, are silent as to the requirements imposed on OIG prior to withholding payment. Furthermore, they do not disclose their *process* for *verifying* the credible allegation of fraud.

For example, proposed section 371.1709 (b)(3) would authorize OIG to impose a payment hold "upon receipt of reliable evidence that verifies a credible allegation of fraud." This misstates the requirement—it is not the "receipt of reliable evidence" alone that verifies a credible allegation of fraud, but there must be a process followed, pursuant to 42 CFR 455.14 and Tex. Gov't Code section 531.102(f).

CMS writes in its guidance to states publication, "an investigation...regarding the validity of an allegation of fraud does not itself trigger a payment suspension...a payment suspension is triggered when the State determines that an allegation of fraud is in fact credible and refers the matter to its MFCU or other law enforcement agency for investigation..."[6] OIG, however, is attempting to authorize payment hold while it determines whether an allegation is credible.

Furthermore, the proposed rules are silent as to what good cause exceptions should be considered prior to imposing a payment hold. In its bulletin, CMS lists the good cause exceptions pursuant to the final rule, as follows:

> There are several circumstances that, under the final rule, constitute "good cause" for a State to determine not to suspend payments, or to discontinue an existing payment suspension, to an individual or entity despite a pending investigation of a credible allegation of fraud. Good cause exceptions to terminate a whole payment suspension or impose a partial suspension generally include the following:
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> 1. Specific requests by law enforcement that State officials not suspend (or continue to suspend) payment.

[3] 42 CFR 455.23(d)(4) states, " If the Medicaid fraud control unit or other law enforcement agency declines to accept the fraud referral for investigation, the payment suspension must be discontinued..."
[4] 42 CFR 455.23(3)(ii).
[5] See CMS March 25, 2011 CPI-CMSC Informational Bulletin, Guidance to States.
[6] See CMS March 25, 2011 CPI-CMSC Informational Bulletin, Guidance to States.

2. If a State determines that other available remedies implemented by the State could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension.

3. If a provider furnishes written evidence that persuades the State that a payment suspension should be terminated or imposed only in part.

4. A determination by the State agency that certain specific criteria are satisfied by which recipient access to items or services would otherwise be jeopardized.

5. A State may, at its discretion, discontinue an existing suspension to the extent law enforcement declines to cooperate in certifying that a matter continues to be under investigation and therefore warrants continuing the suspension.

6. A determination by the State agency that payment suspension (in whole or in part) is not in the best interests of the Medicaid program.

7. The credible allegation focuses solely on a specific type of claim or arises from only a specific business unit of a provider and the State determines that a suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.[7]

TMA strongly urges OIG to place this language in its proposed rules. CMS states in its guidelines that "CMS recognizes that there may be mistaken or false report of allegations of fraud" and that there is a potential for false allegations. Yet OIG, in dealing with physicians and health care providers who have chosen to serve indigent people of Texas, appears to presume guilt, by omitting language from these proposed rules that would provide balance and fairness, and acknowledge the potential for false allegations.

As previously stated, when OIG receives a complaint of Medicaid fraud or abuse from any source, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.[8] Section 531.102(f)(1) of the Texas Government Code states the office must conduct an "integrity review to determine whether there is sufficient basis to warrant a full investigation." TMA strongly urges OIG to define what its process entails in performing an integrity review.

In that regard, TMA recommends adding a new section 371.1709(f) to define a fair process for performing an integrity review, and that subsection (b)(3), which authorizes the payment hold, be rewritten as follows: "(b) OIG imposes a payment hold against a person: (3) after a credible allegation of fraud has been verified by OIG pursuant to section 371.1709(f), and for which an investigation is pending." TMA recommends that

[7] See CMS March 25, 2011 CPI-CMSC Informational Bulletin, Guidance to States.

[8] 42 CFR 455.14; Tex. Gov't Code section 531.102.

OIG create a new subsection 371.1709(f) to mirror the state law requirements pertaining to its requirements upon an allegation of fraud. This law is found in section 531.102 of the Texas Government Code as follows:

> 371.1709(f)(1) If OIG receives a complaint of Medicaid fraud or abuse from any source, including a "credible allegation of fraud", the OIG must conduct an integrity review to determine whether there is sufficient basis to warrant a full investigation. An integrity review must begin not later than the 30th day after the date the commission receives a complaint or has reason to believe that fraud or abuse has occurred. An integrity review shall be completed not later than the 90th day after it began.
> (2) If the findings of an integrity review give the office reason to believe that an incident of fraud or abuse involving possible criminal conduct has occurred, or that a credible allegation of fraud is reliable, then the office must take the following action, as appropriate, not later than the 30th day after the completion of the integrity review:
> (A) if a provider is suspected of fraud or abuse involving criminal conduct, the office must refer the case to the state's Medicaid fraud control unit, provided that the criminal referral does not preclude the office from continuing its investigation of the provider, which investigation may lead to the imposition of appropriate administrative or civil sanctions; or
> (B) if there is reason to believe that a recipient has defrauded the Medicaid program, the office may conduct a full investigation of suspected fraud.

Furthermore, TMA strongly urges that OIG create a subsection 371.1709(f)(3) that requires OIG, when performing an integrity review against a physician, to use an expert physician panel as used by the Texas Medical Board pursuant to sections 154.056(e) and 154.0561 of the Texas Occupations Code. It is critically important that OIG seek clinical input prior to implementing program integrity measures that if incorrectly applied have the potential to harm a practice's financial viability.

TMA would also recommend placing a cautionary and balancing statement in the rules, as is provided in CMS' publication, as follows:

> Mere errors found during the course of an audit would not rise to the threshold of "an investigation of a credible allegation of fraud" necessary to trigger a payment suspension. Similarly, billing errors that are attributable to human error would typically not rise to the level of fraud.

In these proposed rules, however, the OIG has focused only on its new ability to issue a payment hold, and has stripped itself of its obligations to ensure that allegations are verified. Indeed, these proposed rules clearly

state that OIG believes it does not even need "prima facie evidence" to issue a payment hold.[9] The potential for abuse of power by this state regulatory agency is chilling, particularly at a time when more physicians are leaving Medicaid, many out of concern of being inaccurately accused of waste, fraud or abuse with minimal due process. TMA urges OIG regulations to reference a very clear and definite threshold that OIG must cross to "verify" a credible allegation of fraud, as discussed above, and to clearly define its obligations, limitations, and process in regard to initiating a payment hold. Not every allegation of fraud will be credible, and OIG must show that it is using restraint before potentially forcing an innocent provider to close his or her doors due to a payment hold.

TMA opposes section 371.1709 as proposed, and recommends that OIG place the checks and balances that are provided by federal law and rules, and Texas law. The proposed rules as written without affording a provider substantive rights and procedural due process protections, are not in compliance with the federal regulations or with Texas law, and are patently unfair. TMA urges OIG to make these recommended changes to allow transparency to the program, and to cultivate a perception of fairness among providers with regards to the OIG's activities.

Section 371.1709(a)(3). Section 371.1709(a)(3) provides that OIG may impose a payment hold against any person whom it establishes, by prima facie evidence, is "affiliated with" a person who commits a program violation. In addition to TMA's objections pertaining to OIG's proposed process for initiating a payment hold, TMA objects to a person being penalized for the actions of another over whom the person has no control. Penalties based on an affiliate relationship, defined very loosely in these proposed rules as discussed below, is very concerning and unfair. TMA urges OIG to remove subsection (a)(3).

Section 371.1603 Program Authority

TMA strongly opposes proposed rule **371.1603(c)** which reads as follows: "OIG may take administrative enforcement measures against a person *or an affiliate of a person* based upon an *investigation or finding, including an audit finding*, in the Medicaid or other HHS programs." This proposed rule is overly broad and unfair, and allows enforcement measures against an affiliate of a person, and also allows those measures to be based upon a "finding," which is not defined. Because enforcement measures such as administrative sanctions require OIG to afford the provider due process and substantive rights, allowing enforcement measures to be based simply upon a "finding" or investigation, would violate these important rights.

[9] See discussion regarding proposed Section 371.1603(f)(3).

Furthermore, TMA opposes OIG taking administrative enforcement measures against an *affiliate of a person*, as this provision greatly would expand the powers of OIG. Indeed the current rule being repealed provides the following: "The Inspector General may take action against *any provider or person associated with any HHS program* or service as it relates to fraud, abuse, overpayment, waste, or *program violations that rise to the level of fraud*, abuse or waste of those HHS programs or services, or for any of the violations for which the Inspector General may take action against providers or persons associated with the Medicaid program, as described in this subchapter." See rule 371.1603(c). Although the current rule ensures that OIG's authority is paired with providers and persons associated with the HHS program, the proposed rule would allow unwarranted adverse action against persons over which the sanctioned provider would have no control. The preamble to the rules states that Texas Government Code section 531.102 authorizes the proposed substantive requirements, however, section 531.102 does not require the OIG to expand its power to affiliates. The proposed definition of affiliate, found in section 371.1607(2), includes very ill-defined, vague and nebulous relationships, and in some cases no meaningful relationship at all. There is no nexus or "control" that would support a sanction of one as a result of actions of the other.

TMA strongly urges OIG not to adopt its proposed section 371.1603(c), but rather to maintain the language found in current section 371.1603(c).

Proposed rule **371.1603(f)** contains extremely broad, troubling and unfair language, and TMA is very strongly opposed to it. Proposed rule 371.1603(f) provides the following:

> (f) OIG may take administrative actions, sanctions, or both against a person or an affiliate of a person who commits a program violation."

Additionally, the current rule 371.1603(c) (being repealed by these rules) clearly provides that OIG may take action concerning program violations that *rise to the level of fraud.* The proposed rules, however, remove that threshold and allow action against a provider (or an affiliate) for *any* program violations, regardless of whether they rise to the level of fraud. Furthermore, the proposed rule section **371.1607(57)** defines "program violation" extremely broadly, as follows:

> Program violation—A failure to comply with a Medicaid or other HHS provider contract or agreement, the Texas Medicaid Provider Procedures Manual or other official program publications, or any state or federal statute, rule, or regulation applicable to the Medicaid or other HHS program, including any action that constitutes grounds for enforcement as delineated in this subchapter that

forms the basis for an investigation, audit, or other review or that results in a notice of potential or final adverse action for cause."

Thus the OIG is proposing to expand its authority to take administrative sanctions (such as payment hold) against a person or affiliate of a person who commits a program violation as simple as the unintentional failure to inform HHSC of a change in address, for example. Such an aggressive definition of "program violation" will chill physician participation in Medicaid and other HHS programs as few practices, if any, could conceivably avoid occasionally failing to comply with the vast, often confusing, Medicaid program rules. The sheer complexity of the Medicaid program alone means unintended mistakes will be made, which the rules do not appear to recognize. As such, TMA strongly opposes the proposed section 371.1603(f), and recommends that OIG maintain its current rule 371.1603(c).

Section 371.1603(f)(1) provides factors that OIG will consider in determining "whether to open a full scale investigation or administer appropriate administrative actions and sanctions." Although TMA appreciates this list of factors for OIG to consider, TMA requests OIG to clarify and broaden when these factors will be considered. In that regard, TMA requests that the language of proposed rule 371.1603(f)(1) be changed to read as follows:

> "OIG will consider the following factors in determining 1) whether to open a full scale investigation; 2) whether to initiate settlement discussions and enter into a settlement; 3) whether administrative actions and sanctions are appropriate, and if so, which action or sanction is most appropriate; and 4) whether overpayments may be collected through installments or a lump sum:"

In that regard, rule **371.1603(d)(1)** provides that the OIG may, "at its discretion," initiate settlement discussions with the person who is the subject of the investigation. TMA recommends that OIG use the factors listed in (f)(1) to make this determination, as stated above, and that the factors listed in (f)(1) be referenced in this subsection.

Likewise, rule **371.1603(h)** provides that at OIG's "sole discretion, overpayments may be collected in a lump sum or through installments." TMA recommends that subsection (f)(1) be referenced in this subsection, such that the criteria listed in (f)(1) can be considered in allowing for payments through a payment plan. As stated previously in this letter, not all overpayments are the result of fraud or abuse, and these rules should reflect that fact as the current rules do. In fact, TMA recommends that this proposed rule be rewritten to read, "Not all overpayments are the result of fraud or abuse. When overpayments occur, OIG may collect those

overpayments in a lump sum or through installments, considering the circumstances of the case and the factors provided in rule 371.1603(f)(1). If an overpayment occurs without a finding of fraud, abuse, or a program violation rising to the level of fraud, then OIG shall offer the provider a payment plan or refer the matter for routine payment correction by the fiscal agent." Indeed, OIG removed similar language from its informal draft of these proposed rules, and TMA recommends that these protections be afforded to a provider and such language be clearly placed within these rules.

Rule 371.1603(f)(2) lists available administrative enforcement measures, including subsection D which significantly expands on the authority for assessing damages. It allows OIG to assess "costs related to an administrative appeal, and investigative and administrative costs." TMA is strongly opposed to this unfair expansion of potential penalties. This language does not appear in the current rule, found in section 371.1603(3); furthermore, there is no mention of assessing such damages as requiring due process notice and hearing requirements, as is stated clearly in the current rule. Taken to its extreme interpretation, an affiliate or its provider can be assessed the costs related to an administrative appeal, investigative and administrative costs, from a full blown investigation, if all that is found is a simple or technical program violation, such as the violation of a minor requirement found in the manual. There is no requirement that a program violation rise to the level of fraud, yet the penalties here are severe and extensive, and could ultimately put providers out of business. With this proposed provision, OIG shifts the burden of its costs, administrative and investigative costs included, to a provider that is not guilty of fraud. This would chill the provider's right to an appeal, effectively deterring a provider from exercising his or her right to an appeal. TMA strongly urges the OIG to not adopt this proposed rule, and to retain the current definition found in section 371.1603(3).

Section 371.1603(f)(3) is one of the most troubling provisions in these proposed rules, and TMA strongly opposes it as proposed. This proposed section seeks to allow the "sanction of payment hold before establishing prima facie evidence." An innocent provider can be put out of business, without a finding, or even verified evidence, of fraud or abuse and prior to providing substantive rights and procedural due process. TMA incorporates its previous comments pertaining to payment hold herein, but also strongly oppose the language in this subsection and recommends that it be stricken.

The proposed definition of "prima facie" is found in proposed section 371.1607(54), and states: "Prima facie—Sufficient to establish a fact or raise a presumption unless disproved." Incredibly, the OIG has proposed to have the authority and power of imposing the sanction of payment hold against a provider for which there is not even sufficient evidence to establish a presumption. This is akin to no threshold at all. This is outrageous, and TMA strongly opposes section 371.1603(f)(3).

Section 371.1605 Provider Responsibility

Subsection (a). Subsection (a) provides that a Medicaid or HHS provider is responsible for: (1) the provider's own actions and omissions; and (2) "the actions or omissions of the provider's affiliates, employees, contractors, vendors and agents." TMA strongly opposes subsection (a)(2) because it is overly broad, in that a provider would be held accountable for the actions of others, even individuals and entities who are free from the provider's direction or control.

A provider should not be responsible for the actions of those over whom he or she has no control or direction, such as contractors, vendors or agents. In a situation where fraud is alleged, it is even more serious and important that a provider not be placed in a "strict liability" situation in which he or she is liable for actions for which he or she has no way of knowing, or right to know. A provider should be responsible for exercising ordinary care and reasonable diligence, but not for the fraud or program violations of another nor for the actions and omissions of persons over whom he or she has no control or direction.

The rule currently in effect, section 371.1615, provides that a provider is responsible for employees, contractors, and agents. Although TMA opposes one being responsible for contractors or agents, because contractors are by definition independent and not under the control of the person hiring the contractor, and agents can have a limited scope of agency, these proposed rules expand this obligation even further into affiliates and vendors.

In that regard, TMA strongly suggests that subsection (a)(2) be struck.

Subsection (b). This subsection charges Medicaid and other HHS participants with knowledge of various laws, manuals, regulations, bulletins, etc. TMA opposes this language because it is overly broad and requires an unattainable level of knowledge. There is not a person in HHS or a provider in Texas that could truthfully say that he or she knows all the laws, rules, etc. that are in place affecting the Medicaid program. This is a legal fiction that states a requirement that is not attainable. It is like telling a United States taxpayer that, "in filing your return, you affirm that you know all the tax laws, IRS rules, bulletins and policies governing the federal income tax return." These are all put into operation through forms and instructions to taxpayers, and taxpayers are encouraged to consult the IRS for information and interpretations of the various provisions. No one knows it all. Even when one consults and IRS agent, the agent will look up the relevant rule, form or policy, before providing guidance to the taxpayer.

Further, TMA is concerned that subsection (b)(1) is not limited in scope to federal and state laws, rules, and regulations pertaining to Medicaid or other HHS programs with which the person participates. Therefore, TMA requests that the word "including" be struck from subsection (b)(1).

TMA recommends that subsection (3) be limited in scope to "published and publicly available HHS program and procedure manuals with which the person participates." An individual should not be charged with knowledge of manuals and publications for a program with which the person does not participate, or which are not published and available.

Furthermore, TMA recommends that subsection (5) clarify that that the provider agreement or application be "signed by the provider." In this way the provider cannot be held accountable for an agreement or application which he or she did not sign.

Finally, TMA recommends that in subsection (6), "or publicly available policy" be stricken, as it is unclear what is meant by "policy"; any relevant policy will be referenced in the managed care contract, so it should be sufficient to only reference the contract in subsection (6).

Section 371.1607 Definitions

TMA has serious concerns with many of the definitions in section 371.1607. Some of the definitions are unnecessary, as they define words that have plain meaning, while others provide overly broad and unreasonable meanings.

Subsection (1) Abuse. TMA is of the opinion that this definition is overly broad. TMA is aware that this definition partially mirrors the definition found in 42. C.F.R. 455.2, but the proposed definition is much broader. The federal definition, for example, does not define "abuse" to include "do not meet standards required by contract, statute, regulation, previously sent interpretations of any of the items listed, or authorized governmental explanations of any of the foregoing." TMA recommends that this language, which greatly expands the definition of abuse from that found in the federal law, be struck.

Adequate documentation. TMA supports and appreciates OIG striking the proposed definition of adequate documentation from the informal version of these rules, as this definition has a plain meaning and the Medicaid Provider Manual will go into detail regarding documentation required for all of the relevant issues.

Subsection (2) Affiliate/Affiliate Relationship. TMA strongly opposes the definition of affiliate/affiliate relationship and the use of the term in these proposed rules. This term is not defined in 42 CFR §455.2. Although TMA is aware that a definition of affiliate and affiliate relationship currently exists in the rules, and is broad, these rules are being repealed and they are therefore open for comment. The proposed definition would make people affiliates who have a very nebulous connection. For example the proposed definition includes relationships such as an agent or consultant, one with "administrative influence," and persons who share a franchise name.

An affiliate relationship should be determined on the basis of control, especially when one is potentially charged with fraud and abuse based on the actions of an affiliate. If the relationship for purposes of these rules is not based on control, then the behavior cannot be deterred by the other. If one does not have any control or influence over another entity, then they should not be charged with being affiliates nor should they otherwise be held accountable for the other's actions. Indeed, other provisions in Texas law base an affiliate relationship on control.

For example, section 1.002 of the Business Organizations Code defines "affiliate" as: a person who controls, is controlled by, or is under common control with another person. Likewise, section 823.003(a) of the Texas Insurance Code defines an affiliate as follows: A person is an affiliate of another if the person directly or indirectly through one or more intermediaries controls, is controlled by, or is under common control with the other person.

But this proposed definition not only contains overly broad language from the definition currently in place, but also expands that definition more. An affiliate relationship should not be based on indirect ownership of 5%, for example.

Furthermore, subsection (I) is expansive. If it is to be kept, which TMA opposes, TMA alternatively recommends the following: "shares the following identifying information with a person: tax identification numbers, social security numbers, national provider numbers, Texas provider numbers, or bank accounts.

The repercussions of a finding of fraud or abuse, or even a program violation, are so significant that they should not attributed to somebody based on a loose association with another. Indeed, even a payment hold based on a credible allegation of fraud of an affiliate is enough to close a provider's doors permanently.

TMA opposes the use of an affiliate relationship in these proposed rules. While TMA appreciates the effort made after the stakeholder input of the informal rules, this definition should be tightened even further if not removed completely.

Subsection (4) At the time of the request. TMA opposes this definition as this phrase is plain English that need not be defined. Furthermore, the proposed definition is unreasonable and unfair. OIG proposes that "at the time of the request" be defined as "immediately upon request and without delay." This standard is unprecedented in the law, and leaves no room for reasonableness. TMA therefore recommends that it be stricken.

Subsection (17) Costs related to an administrative appeal. These proposed rules would require a provider to pay for costs related to appeals. The proposed definition is broad in its list of costs, and it does not limit the list, but rather uses the word "include." TMA recommends "include" be stricken and replaced with "means."

The proposed rule provides that a provider who appeals an action by OIG and subsequently loses that appeal is required to pay for costs related to the administrative appeal. There is no comparable provision requiring OIG to pay for the costs related to an administrative appeal in the event the OIG is unsuccessful at the administrative appeal level. By defining "Costs related to an administrative appeal" in this subsection as broadly as is proposed, the effect will be to chill any attempt at an administrative appeal, resulting in a chilling of due process. TMA understands the OIG seeking compensation for frivolous appeals, but this proposed definition is overly broad and unreasonable. TMA therefore strongly recommends that subsections (D) through (H) be stricken. It should be sufficient to limit costs related to an administrative appeal to subsections (A) through (C).

Subsection (18) Credible Allegation of Fraud. This definition is critical to these proposed rules, as payment holds are now authorized for a credible allegation of fraud that has been verified by the state. The proposed definition is subtly different than the federal definition, but the difference is very significant. The federal definition, in 42 CFR §455.2, is as follows:

> Credible allegation of fraud. A credible allegation of fraud may be an allegation, *which has been verified by the State*, from any source, including but not limited to the following:
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> 1) Fraud hotline complaints.
> 2) Claims data mining.

3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

Allegations are considered to be credible when they have an indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

The OIG proposed definition is as follows:

> Credible allegation of fraud-An allegation of fraud that has been verified by the state from any source, including fraud hotline complaints, claims data mining and patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

The federal definition clearly shows that the allegation can be from any source, but the allegation must be ***verified*** by the state. The proposed definition, as written and without commas, defines the term as meaning an allegation is verified from any source including hotline complaints, etc.

The federal definition, and accompanying CMS publications, clarifies that the allegation can be received from any source, but must have an indicia of reliability and then be verified by the state through its process. Once it is verified and forwarded to the Medicaid Fraud Control Unit, can a payment hold can be placed on a provider (or managed care organization). The proposed definition, however, would allow the allegation to be verified from any source such as a fraud hotline complaint. This subtle difference in definition is significant and potentially catastrophic to an innocent physician or provider.

TMA strongly urges OIG to adopt the following definition:

> Credible allegation of fraud--An allegation of fraud from any source that has been verified by OIG pursuant to an integrity review and which is undergoing a full investigation by the Medicaid Fraud Control Unit.

Failure to Grant Immediate Access. TMA recognizes and appreciates OIG's removal of this definition that previously appeared in the informal draft of the rules. TMA supports it being removed from the rules.

Subsection (38) Knew or should have known. This phrase has a plain meaning and should not be defined. Furthermore, the definition proposed is overly broad and confusing.

Additionally, TMA very strongly opposes the last sentence of the proposed definition, which reads, "Proof of a person's specific intent to commit a program violation is not required in an administrative proceeding to show that a person acted knowingly." TMA recommends that this sentence be stricken.

Subsection (40) Managing employee. TMA requests that the word "indirectly" be removed from this proposed definition. A managing employee exercises control, adding "indirectly" to the definition makes it vague and ambiguous. Furthermore, conducting operations of an entity does not mean one has control or a management position. TMA therefore recommends striking "or who directly or indirectly conducts the day-to-day operations of the entity."

Subsection (45) Medicaid-related funds. TMA recognizes and appreciates OIG's removal of subsection (c) pursuant to stakeholder input, pertaining to comingling of funds, which had been included in the informal draft of these rules.

Subsection (48) Overpayment. The definition of overpayment, which is an important definition for purposes of this subchapter, is not limited in scope. Although a list is provided of what an overpayment is, the list is preceded with the word "includes" which does not have a presumption of limitation. The definition of such an important term should be definite, not open-ended. TMA therefore recommends that the word "includes" be replaced with the word "means."

Subsection (49) Ownership interest. TMA recommends that a percentage of more significance be used as a threshold. In that regard, TMA recommends that at least 10% be the amount used to determine whether one has an ownership interest in an entity.

Subsection (56) Professionally Recognized Standards of Health Care. TMA supports and appreciates the OIG's removal from this definition the language regarding FDA, CMS, or PHS treatment modality decisions being a standard of care from the informal draft of these rules. Although TMA strongly supports this removal, TMA still opposes having standard of care defined by a rule, because standard of care is defined by the profession, depends upon the circumstances, and differs based on the community the physician practices in. Texas case law defines standard of care as what an ordinarily prudent healthcare provider or physician would have done under the same or similar circumstances.[10] TMA opposes OIG defining a term that is defined in

[10] See Am. Transitional Care Ctrs. Of Tex., Inc. v. Palacios, 46 S.W.3d 873, 877 (Tex. 2001); Strom v. Mem'l Hermann Hosp. sys., 110 S.W.3d 216, 222 (Tex.App.—Houston [1st Dist.] 2003, pet. denied).

case law. If it is defined, however, TMA requests that OIG adopt the definition provided in case law, or alternatively, that the definition proposed by OIG be modified to add, at the end of the definition, "and the community in which the provider practices."

Subsection (57) Program Violation. A program participant only should be charged with information that is published and publicly available, or with agreements to which he or she is a signatory. In that regard, TMA requests that this definition be amended accordingly. For example, TMA requests that the phrase "published and publicly available" be added to the definition after "other official" on line two. Likewise, TMA requests that "to which the person is a signatory" be added after "HHS provider contract or agreement" on the second line. These requested changes will ensure that a provider is apprised of the information to which he or she can potentially be charged with violating.

TMA opposes the language added after HHS program on the fourth line of the proposed rule. The language prior to that point makes the language which begins, "including any," unnecessary. Furthermore, the language is confusing. It states that a program violation includes an action that constitutes grounds for enforcement as delineated in this subchapter…" This is circular, i.e., a program violation which is grounds for enforcement includes a program violation which is grounds for enforcement. The remainder of the sentence, which refers to an action that forms the basis for an investigation, is also confusing and circular because a suspected program violation should form the basis for an investigation, not the reverse. Therefore, TMA recommends that all language after "other HHS program, on line four, be stricken.

Subsection (67) Reasonable request. TMA is concerned with the OIG's proposed definition of "reasonable request." It is disingenuous and unfair for OIG to define a reasonable request as being whatever OIG deems necessary or appropriate. Reasonable request should not be defined, and if it is, the reasonableness standard should not be only that which OIG believes is reasonable. TMA requests that this definition be stricken.

Subsection (81) Substantial Contractual Relationship. TMA recommends that the definition of a substantial contractual relationship include criteria that establish a relationship that is truly "substantial." Five percent or $25,000 is not necessarily a "substantial" relationship for every entity. TMA recommends that "indirect" be stricken and that the threshold be at least 10% of an entity's total "annual" operating expenses.

Subsection (87) Waste. The words "careless" and "inefficient" in this definition are vague and use of the word "or" makes this definition overly broad and unreasonable. The proposed definition of waste is, "Practices that a reasonably prudent person would deem careless or that would allow inefficient use of

resources, items, or services." Both words "careless" and "inefficient" are not legal terms that are easily defined and are subjective. TMA opposes this broad definition.

Section 371.1611 Due Process

TMA requests that subsection (b) be stricken. Subsection (a) states that a provider be afforded due process remedies when administrative sanctions be imposed. TMA supports subsection (a). TMA supports due process for administrative actions as well. Many of the administrative actions listed are significant and would have a severe effect on a provider's practice. Therefore a provider should be afforded proper due process procedures for administrative actions as well.

Section 371.1613 Informal Review

This section provides the rules a provider would have to follow to obtain an informal review. It states that a person has 30 days to request an informal review. Subsection (e) provides that a provider who is subjected to the imposition of a payment hold must request an informal expedited review and have that request *received* by OIG within 10 days of notice of the hold. This is an unfair requirement for any person receiving notice of a sanction, but especially for a provider who has received notice of a potentially disastrous payment hold. Although a provider subjected to payment hold should receive at least as much time to request an informal review as does any other person receiving notice of a sanction, 30 days, TMA is aware that section 531.102 of the Texas Government Code requires the provider to request an expedited hearing within 10 days . There is a significant difference between requesting within 10 days, and OIG receiving within 10 days. The sanction of payment hold is severe, and requiring a provider to receive notice, interpret its meaning, find counsel to assist in interpreting the procedural rules, meeting with counsel, preparing a request for informal review, mailing the request for informal review, and having that request received by OIG within ten days is incredibly unfair, if not impossible.

Therefore, TMA strongly opposes the 10 day requirement for OIG to receive a provider's request for informal hearing, and recommends that the rule be written to require the provider to send the request within ten days.

Section 371.1615 Appeals

As stated in comments to section 371.15, TMA is opposed to a 10 day requirement for request for an expedited appeal. Furthermore, TMA is opposed to any and all request for appeal or hearing that is measured

by the date which OIG receives the request. As with most legal, state agency, and court ordered deadlines, a person is required to send requests by a certain date—having the person be responsible for the mail system's speed of delivery, etc., to ensure that a document is received by OIG at a certain date is unfair.

TMA strongly opposes the 10 day requirement for OIG to receive a provider's request an expedited administrative contested case hearing, and recommends that the deadline be measured by when it is sent.

Section 371.1617 Finality and Collections

Subsection (b)(2) provides that a person can negotiate and execute a payment plan, the terms of which shall be granted at the "sole discretion" of OIG. TMA requests that OIG provide criteria that it will use in exercising its discretion. Considerations should include the severity of the violation, history of compliance, amount of sanction, ability to pay, etc. TMA recommends that OIG list its criteria in this rule and exercise its discretion in favor of cooperation and to encourage program participation by providers.

Subsection (c) sates that the debt will be delinquent and vendor holds may be placed on the provider's claims unless a payment plan is executed by all parties or full restitution is received in 30 days. Subsection (b), however, provides that a person can file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both. If a petition for judicial review is filed in accordance with subsection (b)(3), then the final sanction should not create a final debt. If a provider has filed a petition for judicial review, then a provider should have the opportunity to exercise the judicial process prior to being subjected to the effects of a "delinquent debt."

TMA, therefore, recommends that subsection (c) provide, "If a final payment plan agreement is not executed, full restitution paid, or a petition filed for judicial review, pursuant to subsection (b)(1)-(3), the debt will become delinquent." It would be a due process violation if a provider was not afforded the right to proceed with a judicial review prior to debt collections.

Subsection (e) provides a list of collection methods that OIG may use when a debt is considered delinquent. TMA requests that OIG replace "may include" with "are." The word "include" is a term of enlargement and TMA is concerned that there could be unfair collection practices the OIG could claim it is entitled to, not listed in the rule, because the list is not limited.

Section 371.1621 Provider Enrollment

Subsection (a) (2) provides enumerated considerations the OIG can use in making an initial enrollment determination. Subsection (a)(2)(F) provides that all of those considerations can be made in relation to the provider's or person's family member and member of household. TMA objects to this overly broad consideration, in that it is an invasion of privacy into a potential provider's family and is irrelevant. TMA encourages provider participation in the Medicaid program, but a provision such as this would arguably deter potential providers' participation. TMA therefore recommends that subsection (a)(2)(F) be stricken.

Section 371.1623 Criminal History Checks

Subsection (a) is overly broad and confusing. It states that the OIG may conduct a criminal history check on any person who meets the definition of "indirect ownership interest" which is defined in section 371.1607 as" "Any ownership interest in an entity that has an ownership interest in another entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the entity at issue."

This is an outrageous exercise of government power, as written, and is an invasion of privacy. This subsection does not limit the OIG's power to any meaningful relationship or basis, and does not require OIG to even provide notice that an individual is being subjected to a background check. TMA opposes subsection (a) and recommends that it be stricken.

Section 371.1651 Provider Eligibility

This section provides a list of actions which would subject a provider to administrative actions or sanctions. Although they are not called "program violations" in this section, the definition of "program violation" in these rules includes actions that are grounds for enforcement in this subchapter; thus, all of these enumerated grounds for enforcement are program violations, and they also potentially subject a provider to sanctions—including the sanction of payment hold.

TMA opposes several of these potential violations because they are overly broad or unreasonable, including subsections (a)(2), (3), (4), (6), and (16) and urges OIG to strike these provisions. For example, subsection (16) makes it a violation for someone to not timely update information on a provider enrollment application, provider agreement or amendment, reinstatement request, or any document requested as a prerequisite for

program participation, including change of mailing address or fax number. To make an simple administrative oversight of a hyper technical nature result in sanctions, is unreasonable.

A person should be accountable for his or her actions. Subsection (2) charges a person with having committed a program violation, subjecting the person to a number of potential sanctions, if the person "is affiliated with a person who has been suspended, terminated, or otherwise prohibited from participating in Medicare, Texas Medicaid, CHIP, or other HHS program." This is overly broad and unfair—a person should not be considered to violate the program if an affiliate has been prohibited from participating in one of the enumerated programs. Furthermore, TMA's objection to this subsection is in concert with its objection to the definition of affiliate—a person should not be penalized for that over which a person has no control. TMA strongly urges OIG to strike subsection (a)(2).

TMA strongly objects to subsection (a)(3) and requests that it be stricken. Again, a person should not be penalized for that over which the person had not control. In this case, a person can potentially be charged with a program violation if that person is owned by another, regardless of how insignificant that ownership interest may be, and regardless of whether that ownership interest has comes with any control or influence. TMA objects to subsection (a)(6) for the same reasons. Subsections (a)(3) and (a)(6) are unfair and unreasonable, and TMA requests that they be stricken.

Subsection (a)(4) provides that a provider commits a program violation if any person with an ownership interest in the provider (regardless of amount or control) or an agent or an employee fails to submit "timely and accurate information" during the provider screening process. This provision is very broad and subjective. Again, a provider is potentially liable for the actions of a person over whom the provider has no control, or of a person who has no control over the provider. Furthermore, the potential violation could be as simple providing information that has a reasonable delay or a reasonable omission of information. TMA strongly opposes subsection (a)(4) and requests that it be stricken.

Section 371.1653 Claims and Billing

Subsection (3) provides that a person commits a program violation if the person submits a claim for payment without obtaining prior authorization. This subsection is overly broad and should be stricken. If prior authorization is required, but not obtained, the penalty should be that the claim is not paid—this should not be a "program violation." The rules regarding prior authorizations, such as whether a drug requires prior authorization or a step therapy, are often confusing, particularly since the requirements often vary between

Medicaid fee-for-service and Medicaid HMOs. A provider who does not obtain prior authorization in this instance may have committed an error, but should not be subjected to it being a "program violation" with all of its incident penalties and consequences.

Likewise, subsection (4) considers an administrative claim error a program violation. If a provider inadvertently fails to include an NPI number, this is a billing mistake, not a "program violation." Physicians sometimes make billing errors. The consequence of a billing error or failure to obtain prior authorization is withholding payment for that claim, and this is a significant deterrent and consequence for the error. This should not, however subject the provider to the consequences of having committed a "program violation."

Furthermore, subsection (14) should be stricken, because it appears to be misplaced. Subsection (14) refers to damages, costs, and penalties—which are all remedies—rather than a prohibited action.

Therefore, for the reasons stated above, TMA strongly urges OIG to strike subsections (3), (4), and (14).

Section 371.1655 Program Compliance

TMA recognizes and appreciates OIG not including a provision, which had been included in the informal draft of these rules, which considered it a program violation if one had been inactive as a result of having submitted no claims or no referrals that resulted in HHS program claims for a period of 12 months. TMA had requested that OIG delete such language, and appreciates OIG having done so. There are many circumstances in which a person may not submit claims, such as illness, injury, family emergencies, etc. This should not be a "program violation" that would subject a person to penalties.

Subsection (3) makes failure to repay an overpayment or other assessment after receiving notice, a violation. This is overly broad. A provider should receive due process, a hearing and substantive rights; this provision makes notice the final determination, does not account for any right of hearings or appeals, and does not have a reasonable timeframe to pay, i.e. the provision reads as though there is a violation the day following notice. TMA recommends that this subsection be rewritten to clarify that it is pursuant to exercising due process rights, and to provide a timeframe after the final notice to repay.

Subsection (5) and (6) require a provider to comply with GAGAs, generally accepted government accounting standards. This provision is nonsensical. Perhaps OIG intended GAAP to apply, which is overly burdensome for many practices. TMA recommends that this provision be stricken.

Subsection (9) should clarify that the policies, bulletins, manuals, or interpretations should be "published and publicly available" and that any agreements or contracts to which a provider is held accountable should be signed by the provider. TMA requests that OIG amend this subsection with such clarification.

Subsection (25) provides that a person commits a program violation if the person fails to screen all employees and contractors for exclusions on a "monthly" basis. TMA requests that this verification be required on a quarterly basis.

Subsection (29) is overly broad and unreasonable. It provides that a person has committed a program violation if the person does not refund Medicaid for dollars spent for an excluded person's "salary, expenses, or fringe benefits paid during the period of exclusion." This is grossly unreasonable. A person should be required to repay, if necessary, for overpayments or pay penalties, etc., but it is unfair and unreasonable to require a person to refund Medicaid for an excluded person's salary, fringe benefits, or expenses. These amounts are not paid by Medicaid and should not be refunded to Medicaid. They are not related to the services paid for by Medicaid. TMA urges OIG to strike this subsection.

Section 371.1659 Compliance with Health Care Standards

Subsection (3) provides that a person commits a program violation if the person orders services that substantially exceed a recipient's needs. As written, this provision appears to penalize a physician for providing exceptional services. What "substantially exceeds" a recipient's needs is subjective, and this provision will deter a physician willing to provide exceptional care or go beyond what is minimally necessary to care for a patient. TMA opposes this language and recommends that it be stricken.

Furthermore, subsection (3) provides that a person commits a program violation if he or she orders services that "are not provided economically." This is a vague provision, and is rationing of care. A physician's primary responsibility is his or her patient's care. TMA supports providing care based on the patient's needs, not based on who the payer is. This provision would at times require a physician to choose between exercising in accordance with the standard of care and in accordance with medical ethics, or alternatively in accordance with economic based rationing. TMA opposes this language and recommends that it be stricken.

TMA recommends that all of subsection (3) be stricken. The alleged violations in subsection (3) should not be considered "program violations," subjecting a provider to potential sanctions. If the program denies

payment, that is one thing, but to penalize a provider as having committed fraud, abuse, or a "program violation" in these circumstances is unreasonable, unnecessary, and unfair.

Subsection (4) provides that a person commits a program violation if the person is the subject of a "voluntary" action taken by a licensing or certification agency or board. TMA requests that the "voluntary" language be removed, and that it only be a violation if a severe "involuntary" adverse action is taken, such as a license revocation or suspension. There are numerous very beneficial programs, such as the physician health program, that are based on a physician voluntarily entering the program. In the case a license is taken or suspended due to this voluntary submission, the result should not be a Medicaid "program violation." TMA opposes the word "voluntary" in subsection 4, and urges OIG to strike "voluntary" from subsection (4).

Finally, subsections (8)-(10) appear to be referring to privacy laws under section 181 of the Texas Health and Safety Code. TMA opposes listing a portion of the privacy law in this subsection, but rather requests that reference simply be made to the state law provision. In that way, as the law develops and cases and rules interpreting the law are issued, a provider will be afforded those interpretations. Placing a portion of this law into these proposed rules will put a potentially confusing and conflicting parallel requirement in effect. TMA therefore recommends that OIG refer to the law, as it did in subsection (7) by referring to HIPAA.

Section 371.1663 Managed Care

TMA notes and appreciates OIG removing language TMA opposed in the informal draft rules, which would have allowed a MCO to delay payment up to 45 days. TMA supports the language in the proposed rules, which requires a MCO to comply with its contract and to not cause a delay in making payment.

Section 371.1667 Records and Documentation

Subsection (3) provides that a person commits a "program violation" if the person fails to grant "immediate access" to the premises, records, documentation or "any items or equipment determined necessary by the OIG…" The requirement for "immediate access" is unreasonable, and does not account for or provide any exception for reasonable delay, patient safety, etc. There are a plethora of examples in which a physician may be unable to provide "immediate access" and should not be penalized for failing to do so. TMA recommends that "immediate" be removed from this language, and that language be added to provide to allow exceptions when there is a good faith effort at compliance, but circumstances prevent an immediate access.

Section 371.1669 Self Dealing

Subsection 10 provides that a physician commits a program violation if the physician refers to an entity with which the physician has a financial relationship for the furnishing of designated health services. TMA is concerned about the potential impact this provision will have on a physician's participation in an Accountable Care Organization under the Patient Protection and Affordable Care Act, or a Health Care Collaborative under Texas law.

Furthermore, this section appears to be mirroring the federal anti-kickback law, yet it fails to adopt exceptions and the federal safe harbors. The federal safe harbor regulations describe business practices that are not treated as offenses, even though they potentially implicate the federal anti-kickback statute. TMA recommends that subsection (10) be removed, and that the body of law, including the federal safe harbors be referenced and included in this section.

Section 371.1701 Administrative Actions

Subsection (e) provides that an administrative action does not give rise to due process, additional notice, or hearing requirements. TMA strongly objects to this subsection. Administrative actions under this section are significant, and should require the same due process protections, notice requirements, and hearing requirements that are afforded for administrative sanctions, and TMA urges OIG to provide those protections for administrative actions.

Additionally, TMA opposes subsection (a)(4) because it subjects a person to administrative actions based solely on an affiliation. This is unfair and TMA strongly urges OIG to strike this provision, as it will punish one without any evidence of his wrongdoing, does not include a threshold of control, and will not deter any action, since the one being punished has not committed the violation.

TMA also opposes subsection (a)(3) because it causes waste and overpayment to be subjected to program actions. As stated previously in this letter, overpayments are not always the result of wrongdoing, and could be based on simple billing or clerical errors. Furthermore, the definition of waste is overly broad, as previously discussed, in that one can cause waste by simply being "careless."

Finally, TMA opposes use of the word "include" in subsection (c), which precedes the list of potential administrative actions available to OIG. TMA recommends that a limiting word such as "are" be used to replace "include."

Section 371.1703 Termination of Enrollment or Contract

TMA objects to subsection (b)(1), (b)(4), and (b)(7), and (b)(8)(c) for the reasons previously offered in this letter. TMA objects to a provider being held accountable for the actions of another over whom the provider has no control, or of another who has no control over the provider. These subsections require OIG to terminate the enrollment or contract from Medicaid or other HHS program, based on the actions of another. Such a policy is fundamentally unfair, and does nothing to deter future violations. For example, subsection (b)(1) would terminate a provider, when a person with the ownership interest in the provider has been convicted of a criminal violation within the last ten years. Typically, in law, the criminal act of another does not subject one to vicarious liability, and it is often an intervening cause precluding liability for the one who did not perform the act. Indeed, in this example, a person could have no knowledge of wrongdoing and have no influence over one who has an ownership interest in him, yet be terminated because that partial owner committed a crime. TMA recommends that OIG strike this subsection.

Likewise, subsection (b)(4) subjects one to termination when another with ownership interest fails to submit "timely and accurate information." Again, an individual will be subjected to a mandatory termination based on the actions of another, over whom the individual has no control. TMA urges OIG to strike these subsections. TMA has the same concerns with subsection (b)(7) and (b)(8)(c) and likewise opposes these sections and recommends that they be stricken.

Furthermore, TMA objects to subsection (g)(6)(B). TMA understands the OIG making termination effective on the notice of termination when the health or safety of a person is at risk. However, failure to grant "immediate" access to OIG or a Requesting Agency, or failing to provide copies, etc. does not warrant this harsh penalty. TMA objects to OIG making its activities, requests, and time of requests at the utmost importance in this program. TMA requests that OIG allow for reasonable compliance, make exceptions in certain circumstances, and be open to good faith efforts at compliance with OIG's requests. TMA requests that subsection (g)(6)(B) be stricken.

Section 371.1705 Mandatory Exclusion

Subsection (b) provides that OIG may exclude a person without sending prior notice under certain circumstances. TMA objects to the exclusion of a person without sending prior notice. TMA appreciates the need to have an exclusion when the health or safety of a person is being placed at risk, but strongly objects to mandatory exclusion without prior notice for those reasons enumerated in subsection (b)(2), such as failure to grant "immediate access," failure to provide "copies or other items," or "failure to allow a requesting agency to conduct duties that are necessary to performance of their statutory functions." Therefore, TMA opposes subsection (b)(2) and TMA recommends that it be stricken.

Subsection (e)(1)(I) provides that an exclusion is retroactive if an administrative law judge upholds an exclusion. TMA opposes this provision. If the person files a timely appeal, the date of the exclusion should be when the administrative law judge upholds the exclusion. To allow otherwise would chill the ability of a provider to have an appeal in good faith. A good faith appeal that is unsuccessful, should not subject a provider to more penalties and violations that would occur if the provider had participated in the program during the pending appeal. TMA opposes this provision and recommends that the exclusion be effective upon a final determination by an administrative law judge, if the provider has appealed.

Subsection (e)(4)(D) provides that an excluded person is prohibited from "accepting employment by any person whose revenue stream includes funds from a Title V, Viii, XIX, XX or CHIP program." This prohibition seems overly broad and harsh. If the person is not obtaining any benefit or income from these programs, the person should not be prohibited from being employed by an entity who receives income from these programs. Indeed, this prohibition is absolute, regardless of how small or insignificant the income stream to the entity is. TMA opposes this provision, especially in light of consolidation of medical practices and increased physician employment. If a physician is excluded, it could be very difficult for a physician to find employment from an entity that does not have revenue from one of these sources. This exclusion is not limited in time, is overly broad and unreasonable. TMA recommends that it be stricken.

Section 371.1707 Permissive Exclusion

TMA reiterates its objections to section 371.1705 here, as this section mirrors section 371.1705. In that regard, and for the same reasons stated above, TMA objects to subsection (b), which allows OIG to exclude a person without sending prior notice of intent to exclude. TMA urges OIG to always send a notice of intent to exclude. TMA objects to subsection (e)(1)(D), which makes an exclusion after an administrative appeal

retroactive. Finally, TMA objects to subsection (e)(4)(D) which prohibits an excluded person from "accepting employment by any person whose revenue stream includes funds from a Title V, Viii, XIX, XX or CHIP program."

Section 371.1711 Recoupment of Overpayments and Debts

Subsection (b)(3) provides that OIG may recoup from any person who it establishes, by prima facie evidence, is "affiliated with" a person who commits a program violation that leads to the payment of an overpayment. TMA objects, as stated previously, to a person being penalized for the actions of another over whom the person has no control, and who has no control over the person.

Subsection (e) provides that the person who is the subject of a recoupment is responsible for paying the overpayment amounts, "plus OIG's or other HHS program's costs related to an administrative appeal and all investigative and administrative costs related to the investigation that resulted in recoupment, if applicable." TMA strongly objects to and opposes this provision. This is patently unfair and unreasonable. Furthermore, a provider should not be required to pay for OIG's costs in an appeal. The appeal is a due process right afforded to the participant, and the potential repayment of these costs would effectively chill this important due process protection. There is no provision included which would require OIG to repay the provider's costs if the provider's appeal is successful.

Section 371.1713 Restricted Reimbursement

TMA opposes and objects to subsection (a)(2) for the same reasons previously stated. This subsection penalizes a provider for a violation committed by an "affiliate." Control is the issue, and the appropriate definition of affiliate is essential. TMA directs OIG to its previous comments on this issue.

TMA opposes and objects to subsections (e)(3)(C) and (e)(4) for the same reasons stated previously in this letter. Regarding (e)(4), again, a provider should not be penalized for an administrative appeal by having the effective date made retroactive.

Section 371.1715 Damages and Penalties

Subsection (e) provides the assessment of damages and penalties. TMA is concerned with and opposes the excessiveness of the penalties in subsection (1)(B). OIG is considering items that may be simple mistakes as

program violations, and providers will be potentially liable for damages and penalties disproportionate to the "violation" or mistake. TMA also opposes subsection (e)(3) which requires a person against whom damages or penalties are assessed to pay for OIG's or other HHS program's costs related to the investigation.

TMA urges OIG to make this program accessible to physicians, and not create a deterrent based on the fear of OIG's process, fines, penalties, alleged violations, etc. TMA also urges OIG to show good faith by writing these rules to clearly show balance and fairness. TMA is committed to supporting the Medicaid program with education and to encourage physicians to participate but is concerned by the tenor and breadth of these proposed rules.

Section 371.1719 Recoupment of Overpayments Identified by Audit

In order to ensure that OIG audits are fair and transparent, TMA urges OIG to adhere to certain fair audit principles. For example, TMA recommends that the following be included in subsection (b)(1)(C), pertaining to notice of an audit:

> Auditors should provide physician practices with advance written notice sent by certified mail at least 30 business days before an audit. The audit notice must clearly identify the HHS program on whose behalf the audit is being conducted; the type of audit; the names and contact information for the auditors; and, in the case of audits conducted by outside contractors, the name and contact information of the responsible individual with the contracting payer. In addition, the notice must cite to the legal authority under which it is being conducted, which may include a federal or state law or regulation, a contractual provision, and/or a section in a payer's policy manual readily assessable by the practice.
>
> The notice must also clearly designate the records to be reviewed (e.g. patient name, date of service, etc.) If the auditor intends to review records for a particular code set or a particular modifier, the codes and/or modifiers should be identified.
>
> The notice should state whether the audit will be conducted on-site or whether the practice is required to submit records to the auditor. If the physician practice is required to submit records, the notice should specify the date by which the records are to be submitted. To the extent the records request is limited to specific records, the practice should have the option to submit additional documentation.

The notice should also specify the manner in which the records should be submitted (e.g. paper, electronic, disc, etc) and where the records should be sent.

TMA also urges OIG to add a subsection regarding scheduling the audit, as follows:

If the audit is to be conducted at the physician's offices, it should be scheduled at a mutually convenient time. The audit should conclude or be suspended at the practice's regular close of business unless other arrangements have been made in advance.

Furthermore, it is very important that the auditors be properly qualified. In that regard, it is imperative that OIG place in these rules requirements for the qualifications of auditors, as follows:

All individuals performing medical audits should have appropriate knowledge and experience in coding, including applicable ICD, CPT®, and HCPCS codes; the format and contents of medical records and claims forms; and all applicable state and federal laws and regulations.

Individuals auditing medical records regarding issues of medical necessity should be licensed in a clinical discipline and have the appropriate training and experience to provide the necessary expertise to determine whether clinical tests and procedures were medically necessary without the benefit of examining the patient. Individuals auditing medical records regarding issues of coding and documentation should be certified in coding, with at least one year's auditing and/or coding experience. The names and the credentials of the auditors should be included in the audit report.

The auditors should have no conflict of interest. Except where expressly permitted by federal law (e.g. the RAC auditors), the auditors should not have any financial incentive to find errors.

TMA also strongly urges OIG to place requirements pertaining to the conduct of the audit. Furthermore, TMA opposes subsection (b)(1)(B), which allows an audit to cover a period of five years. TMA recommends OIG placing a subsection in its rules pertaining to the conduct of the audit, as follows:

The audit should be limited to claims submitted within 18 months of the date of the audit, unless a shorter time is dictated by state law.

The auditors must agree to protect personal health information and must adhere to HIPAA and state privacy rules.

The auditors should recognize that the principal business of physician practices is patient care. Accordingly, the auditors should respect physician practices' need to use their equipment and premises to treat patients while the audit is ongoing. For example, auditors should work with physician practices in scheduling time on computer terminals used to access medical records and other office equipment such as printers and photocopiers.

The auditors should advise physicians to review all records before submission. Physicians should be permitted to supplement records when necessary before verifying that the submission is complete.

All records submitted to and/or taken by auditors should be copies rather than originals. Physicians should be compensated for the cost of duplicating records.

Whenever audits are conducted by records submission only, a process should be established allowing for discussion between the auditor and the physician practice prior to issuance of the audit report to clarify issues and to allow for submission of supplemental information.

The proposed rules are also lacking in proper reporting requirements. TMA strongly urges OIG to place the following information into a section pertaining to the Audit Report:

The audit report should clearly identify any errors discovered in the audit, specifying all medical and reimbursement policies used in determining the outcome of the audit. The audit report should note the date of publication and effective date for all such policies. The audit report should also identify underpayments to the physician practice.

The audit report should be provided within the designated timeframe under law or the terms of the relevant physician contract.

Auditors should provide physicians with a copy of the audit analysis in electronic format, such as ASCII, CSV, or Excel. Worksheets should be clearly labeled to allow physicians to identify the fields which were used and any formula applied to those fields.

When errors are found, the audit should be used to educate physicians where appropriate rather than as a punitive tool. The first time that a physician practice is audited, repetition of the same coding error on multiple claims should be viewed as erroneous coding rather than as a manifestation of intent to commit fraud.

If repayment is sought, the audit report should clearly describe how the overpayment amount was calculated. Identified underpayments should be credited in calculating any amounts owed back to the payer.

For physicians who elect to challenge the auditors' findings, the audit report should describe the appeals process, including the deadlines for filing and where to find any required forms. Any required appeals forms should be available on-line. Physicians should not be subjected to 100% claims' review or a cessation in payments while their appeals are pending.

Finally, TMA is aware that OIG often uses extrapolation. It is imperative that physicians be provided with information regarding the extrapolation formula as well as an opportunity to have a review of 100% of their records. In that regard, TMA urges OIG to place the following, pertaining to extrapolation, in the rules:

Physicians should always be afforded the opportunity to have a review of 100% of their records.

If extrapolation is used to calculate an alleged overpayment amount, the extrapolation formula should be provided in the audit report. The name and the credentials of the statistician performing the analysis should also be included in the report.

Extrapolation must be based on a statistically valid random sample, and should use stratification when appropriate. The audit report should disclose how the sample was selected.

All zero paid claims and claims with outliers must be removed from the sample prior to extrapolating any payment due. If the auditor believes that any claims with outliers have been overpaid, those claims should be dealt with individually and outside of the extrapolation process.

Unless the data are normally distributed, approximately normally distributed and/or symmetrical, the median (rather than the average) amount should be used to determine the central data point per unit audited as the basis for calculating the alleged overpayment.

The lower bound of the two-sided 90% confidence interval should be used to calculate the alleged overpayment.

Summary

TMA is concerned about the inequitable approach OIG is taking in these proposed rules.The Medicaid program depends upon having a robust network of physicians and health care providers to ensure that patients receive timely, safe, and high quality medical care. These physicians and providers provide essential services to millions of low-income Texans, though they are reimbursed at a fraction of their costs for doing so. TMA has received repeated verbal assurances from the OIG that it is committed to preserving access to care within Medicaid and other programs, while also achieving its legislatively directed mission to enhance program integrity. Yet, those assurances are not reflected in the language of the rules. It is essential that OIG state plainly within the rules that the agency recognizes that not all mistakes are tantamount to fraud or abuse. Further, the OIG must promulgate rules with reasonable due process. Without such changes, the pervasive fear among physicians that they will be incorrectly accused of fraud, waste or abuse or denied meaningful recourse in a fraud investigation will continue to contribute to the decline in physician participation in Medicaid and other HHS programs.

TMA strongly urges OIG to consider its comments herein and adopt and modify language accordingly. Without significant modification to these proposed rules, Texas physicians will have reason to view this OIG and the Medicaid program from a perspective of fear, which would be detrimental to the Medicaid program and its patients.

Should you wish to meet to discuss the comments further or have any questions, please do not hesitate to contact any of the TMA staff carbon copied below.

Sincerely,

John Holcomb, MD, Chair
TMA Select Committee on Medicaid, CHIP and the Uninsured

cc: Donald P. Wilcox, JD, TMA General Counsel
Darren Whitehurst, Vice President, TMA Division of Advocacy
Lee Spangler, JD, Vice President, TMA Division of Medical Economics
Andrea Schwab, JD, CPA, Associate General Counsel
Helen Kent Davis, Director, Governmental Affairs