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CMS Rule Allowing Payment Suspensions Due to 'Credible Allegation of Fraud' Raises Due Process Concerns

BY HARRY R. SILVER

In a *Federal Register* notice published Feb. 2,[1] The Centers for Medicare & Medicaid Services, together with the Department of Health and Human Services Office of Inspector General, issued final regulations implementing some of the fraud and abuse-related provisions of the Patient Protection and Affordable Care Act (''ACA'').

The final regulations implement the ACA provisions requiring (1) the indefinite suspension of payments to providers if there has been a ''credible allegation of fraud''; (2) the screening of Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers; (3) the imposition of an application fee on institutional providers and suppliers; (4) the imposition of temporary moratoria on the enrollment of new Medicare, Medicaid and CHIP providers if the secretary of health and human services (''the Secretary'') determines that a high risk of fraud, waste or abuse exists; and (5) the termination of Medicare, Medicaid and CHIP providers if they have been terminated by another government payer.

There will be a separate rulemaking on the required elements of an effective compliance program.

These regulations, which were the subject of an in-depth analysis in the Feb. 23 *BNA's Health Care Fraud Report*, will take effect March 25.[2]

This article focuses on the regulations governing the indefinite suspension of payments and the due process concerns they raise.

Suspension of Payments

1. *ACA Authorization*

The rules implement § 6402(h) of the ACA, which authorizes the Secretary to suspend payments to Medicare providers and suppliers ''pending an investigation of a credible allegation of fraud . . . unless the Secretary determines there is good cause not to suspend such payments.'' Section 6402(h) contains a parallel provision requiring state Medicaid programs to suspend payments to providers when an investigation of a credible allegation of fraud is pending against the provider.

[1] 76 Fed. Reg. 5862,

[2] CMS will accept comments on whether to require fingerprinting, as part of the screening process for certain providers, until April 4.

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While CMS regulations authorized the suspension of Medicare and Medicaid payments prior to the enactment of the ACA, § 6402(h) lowers the standard the government must meet in order to suspend payments based upon suspected fraud.

The pre-ACA regulations authorized CMS to suspend Medicare payments to providers for suspected fraud based upon ''information . . . [that] CMS determines . . . is reliable.''[3]

States had been authorized to withhold Medicaid payments to a provider based upon the receipt of ''reliable evidence of fraud.''[4] Under § 6402(h) of the ACA, the new standard, for both Medicare and Medicaid, is ''credible allegation of fraud,''—and the new regulations define this term broadly.

In addition to this lower standard, the new rules raise troubling due process issues. As a result, the rules governing the suspension of payments are potentially the most significant of the regulations published in the Feb. 2 *Federal Register* notice. While the rules governing the suspension of Medicare are similar to those governing Medicaid, there are significant differences.

a. Medicare

The new regulations define ''credible allegation of fraud'' to mean an allegation from any source, such as patterns identified through audits, data mining, investigations under the civil False Claims Act (presumably including *qui tam* complaints by whistleblowers) and incredibly *fraud hotline complaints*.

The definition of ''credible'' is not very enlightening: allegations are ''credible'' when they have an ''indicia of reliability.'' Using this standard, the secretary will determine whether there has been a ''credible allegation of fraud'' after consultation with the OIG.

According to CMS, ''consultation between CMS and the OIG prior to implementing a payment suspension will provide ample opportunity for the credibility of an allegation to be assessed.''[5]

''Good cause'' for not suspending payments has been defined by CMS as (1) specific requests by law enforcement because of the risk of alerting the target, jeopardizing an undercover investigation, or exposing confidential sources such as whistleblowers; (2) jeopardizing beneficiaries' access to medical care; (3) a determination by CMS that there are other, more effective, remedies; and (4) a determination by CMS that a suspension is not in the best interests of the Medicare program.[6]

Because the ACA authorizes a payment suspension until an investigation of a credible allegation of fraud has been concluded, the new rule defines the conclusion of the investigation as the termination of legal action by settlement, judgment, dismissal, or when the case is dropped for lack of sufficient evidence.[7]

While this can lead to an indefinite suspension, the regulations provide that suspensions are to be for a period of 180 days. The 180-day suspension can be extended, however, if (1) administrative action is pending or being considered by OIG; or (2) the Department of Justice requests a continuation of the suspension based on an ongoing investigation and anticipated or pending criminal or civil action.[8]

b. Medicaid

States have long been ''authorized'' to withhold Medicaid payments to a provider based upon the receipt of ''reliable evidence'' of fraud.[9] The ACA now provides that states may not receive federal financial participation in cases in which the state has failed to suspend Medicaid payments to a provider when an investigation of a credible allegation of fraud is pending against the provider, unless the state determines that there is good cause not to suspend payments.[10]

The new regulations implement this statutory provision. While CMS's definition of ''credible allegation'' for Medicaid is virtually identical to that for Medicare, states have the flexibility to determine what constitutes a ''credible allegation of fraud'' under state law.

Moreover, ''State agency investigations, though they may be preliminary. . . are adequate vehicles by which it may be determined that a credible allegation of fraud exists sufficient to trigger a payment suspension to protect Medicaid funds.''[11]

A state is not required to suspend all payments to a provider. CMS will continue its policy of allowing states to suspend payments, in part, to a provider.[12]

The ''temporary'' suspension will continue until (1) law enforcement authorities determine that there is insufficient evidence of fraud on which to base a legal action; or (2) legal proceedings are completed. A state is required to request, on a quarterly basis, a certification from the applicable law enforcement agency that the matter continues to be under investigation or that enforcement proceedings have been initiated and have not been completed.[13]

CMS expressly declined, however, to impose a 180-day initial limit on the duration of a suspension of Medicaid payments similar to the (extendable) time limit imposed on suspensions under Medicare.[14]

In contrast to the procedure governing the suspension of payments by the federal government under Medicare, state Medicaid agencies are required to notify providers of a payment suspension within five days of taking this action. This five-day period can be extended, however, for up to 90 days at the request of a law enforcement agency.[15]

The notice of suspension should reference the general allegations upon which the suspension has been based and should also reference any existing state appeals procedures. States are not required to notify a provider prior to suspending payments.[16]

2. *Due Process Concerns*

The new regulations do not require Medicare providers to receive notice either of the reasons for a suspension or even of the existence of a suspension. In response to comments raising due process concerns,

[3] 42 C.F.R. § 405.372(a)(4).
[4] *See* 76 Fed. Reg. at 5931.
[5] 76 Fed. Reg. at 5929.
[6] *Id.*
[7] *Id.*
[8] 76 Fed. Reg. at 5930.
[9] *See* 76 Fed. Reg. at 5931.
[10] 76 Fed. Reg at 5932.
[11] *Id.*
[12] 76 Fed. Reg. at 5934.
[13] 76 Fed .Reg. at 5933.
[14] 76 Fed. Reg. at 5940.
[15] 76 Fed. Reg. at 5932.
[16] 76 Fed. Reg. at 5932, 5937.

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CMS stated that providers have ''ample opportunity to submit information to us in the established rebuttal statement process to demonstrate their case for why a suspension is unjustified.''[17]

The ''established rebuttal process''[18] requires that providers be given the opportunity to submit a statement setting forth the reasons a suspension should not be put into effect if the provider has been given prior notice. Prior notice is not required, however, if the suspension is based upon suspected fraud.[19] If Medicare payments are suspended without prior notice, the provider is to be given ''an opportunity to submit a rebuttal statement as to why the suspension should be removed.''[20]

Because the new regulations do not require CMS, or any other government agency, to inform the provider of the reasons for (or even the existence of) the suspension, it is unclear just what ''information'' a provider can submit, ''in the established rebuttal statement process.'' CMS fails to address, or even acknowledge, this problem.

While CMS does acknowledge that the Medicaid suspension rules contain a time limit for giving providers notice of a suspension, and that the notice of a suspension of Medicaid payments is to reference at least the general allegations upon which the suspension has been based, CMS's response is simply that ''[t]he Medicare and Medicaid payment suspension rules need not mirror each other in every respect,'' and that CMS has long suspended payments without prior notice and that it has ''an established track record for providing written notice to providers as soon as is practicable.''[21]

CMS also assures providers that the suspension ''authority will be exercised judiciously by CMS, in consultation with the OIG,'' but that ''[t]he mechanics of the consultation between CMS and our law enforcement partners to determine the credibility of allegations will be detailed in a Memorandum of Understanding between the respective agencies and we do not believe it is appropriate to detail this process in the final rule.''[22]

This reassurance by CMS hardly addresses, much less justifies, a Kafkaesque procedure in which (1) a provider need not be notified, for an indefinite period, that its payments have been suspended; (2) a suspension can be based on a subjective standard—any allegation that CMS and OIG find to be ''credible''; (3) when (and if) the provider is notified of the suspension, the notice need not inform the provider of the allegations on which the suspension has been based; but (4) the provider may submit information, in a rebuttal statement, to demonstrate that the suspension is not justified.

A provider cannot even attempt to demonstrate that beneficiaries' access to care will be jeopardized, one of the ''good cause'' exceptions, if the provider is unaware of the suspension.

That being said, the outlook for successfully challenging this procedure is anything but certain.

[17] 76 Fed. Reg. at 5930.
[18] 42 C.F.R. §§ 405.372(b), 405.374(a).
[19] 42 C.F.R. § 405.372(a)(4).
[20] 42 C.F.R. § 405.372(b)(2).
[21] 76 Fed. Reg. at 5931.
[22] 76 Fed. Reg. at 5930, 5931.

3. *Due Process Analysis*

''The essence of 'due process' is notice and a fair opportunity to be heard.''[23] ''The lack of a meaningful opportunity to be heard is at the core of a due process claim.''[24] Under those criteria, the new regulations governing the suspension of Medicare payments would certainly appear to violate elementary due process standards.

Violation of procedural due process standards alone is not itself unconstitutional. Before even addressing whether there has been adequate notice and a fair opportunity to be heard, a court must first decide whether there has been a deprivation of a liberty or property interest.[25]

While some courts have determined that ''[h]ealth care providers have a constitutionally protected property interest in continued participation in the Medicare and Medicaid programs,''[26] this is not the prevailing view.[27] As a result, the new temporary suspension regulations are subject to procedural due process protections only if a provider is found to have a liberty interest in continued Medicare or Medicaid reimbursement.[28] Two California Medicaid (Medi-Cal) decisions are instructive on this point.

California law authorizes suspensions from Medi-Cal while a provider is under investigation for fraud,[29] or if there is reliable evidence, that would be admissible in an administrative hearing, of fraud or willful misrepresentation.[30] In *Guzman v. Shewry*, 552 F.3d 941 (9th Cir. 2009), a provider sought an injunction against his temporary suspension from Medi-Cal, contending that he had a right to a pre-suspension hearing because (1) he had a due process protected property interest; and (2) he had a liberty interest in the right to contract with the state, the right to pursue the occupation of his choice, and in the right to preserve his reputation for honesty and morality.[31]

Under established 9th Circuit precedent, an individual's liberty interest is implicated if an allegation impairs that individual's reputation for honesty and morality, the individual contests the accuracy of the allegation, the allegation has been publicly disclosed, and the allegation has been made in connection with the alteration of a right or status recognized by law.[32]

In *Erickson v. United States ex rel. Dep't of Health and Human Services* 67 F.3d 858, 863 (9th Cir. 1995), the court held that an exclusion from Medicare constituted the alteration of the plaintiffs' ''status'' as participating providers under Medicare.

As a result, plaintiffs' protectable liberty interest was at stake. Nevertheless, in *Guzman*, the 9th Circuit rejected the provider's arguments, ruling that the tempo-

[23] *United States v. Villanueva-Diaz*, 2011 WL 6930001 at *4 (5th Cir. Mar. 1, 2011).
[24] *National Association of Boards of Pharmacy v. Board of Regents*, 2011 WL 649951 at *15 (11th Cir. Feb. 24, 2011).
[25] *Id.; Guzman v. Shewry*, 552 F.3d 941, 953 (9th Cir. 2009).
[26] *Patchogue Nursing Center v. Bowen*, 797 F.2d 1137, 1144-45 (2d Cir. 1986).
[27] *Personal Care Products, Inc. v. Hawkins*, 2011 WL 746357 at *2 (5th Cir. Mar. 3, 2011); *Guzman*, 552 F. 3d at 954.
[28] *Guzman*, 552 F. 3d at 953-54.
[29] Cal. Welf. & Inst. Code § 14043.36.
[30] Cal. Welf. & Inst. Code § 14107.11.
[31] 552 F.3d at 953-54.
[32] *Vanelli v. Reynolds School Dist. No. 7*, 667 F.2d 773,777-78 (9th Cir.1982).

rary deprivation of Medi-Cal reimbursement is not the deprivation of either a protected property or liberty interest. Because *Erickson* involved an exclusion on the basis of a criminal conviction, the court ruled that it was not applicable to Guzman's case.

Significantly, however, the court did point out that Guzman "was notified of his temporary suspension before it was enforced, and that California law entitled him to file a written appeal . . . and [to] a meeting with [Medi-Cal] officials."[33] The purpose of such a meeting is to demonstrate that "the information on which Medi-Cal was relying was erroneous."[34]

In *Mednik v. State Dept. of Health Care Services*, 175 Cal. App. 4th 631, 96 Cal.Rptr.3d 112 (2d Dist. 2009), a state appellate court essentially agreed with the 9th Circuit's analysis, but found a protected liberty interest in being *considered* for a contract.[35]

The court noted that Medi-Cal periodically requires categories of providers to apply for re-enrollment. Fortunately for Mednik, he was one of the providers selected for re-enrollment. While Mednik's re-enrollment application was pending, a fraud investigation was, independently and coincidentally, initiated and Mednik was "temporarily" suspended from Medi-Cal, which made him ineligible for re-enrollment until the investigation had been concluded.

Because the "temporary" suspension had been in effect for years, and because Mednik remained ineligible to be a MediCal provider while the suspension remained in effect, Mednik had suffered a de facto debarment or exclusion. As a result, the court determined that he had been deprived of the due process protected liberty interest in being considered for a contract. Nevertheless, the court ruled that "due process does not always require a hearing before deprivation occurs."[36]

As the 9th Circuit had in *Guzman*, the state court noted that the provider received a letter notifying him of the temporary suspension, of his right to file a written appeal, and that this action was "being taken because Mednik was under investigation for fraud, abuse, or willful misrepresentation. . . . The letter also described the evidence that formed the basis for the investigation." [37] Thus, while Mednik was not entitled to a pre-suspension hearing, the procedure employed by California was sufficient to satisfy due process

The California procedures are in stark contrast to the procedures governing temporary suspensions of Medicare payments by CMS, where providers are entitled to submit a rebuttal statement but are not required to be advised of the reasons for the temporary suspension—or even that a temporary suspension is in effect.

4. *Likelihood of a Successful Challenge to the Regulations*

The ruling in *Mednik*, and the implication in *Guzman*, that the California procedures are consistent with due process certainly suggest that the procedure for suspending a provider from Medicare would be vulnerable to a due process challenge.

Under the *Mednik* rationale, an indefinite suspension is tantamount to exclusion, which could well put a provider out of business. While there does not appear to be a right to a pre-suspension hearing, a provider should certainly, at the very least, have the opportunity to present some kind of rebuttal before potentially being put out of business and jeopardizing beneficiaries' access to care.

[33] 552 F.3d at 951 n.8.
[34] 552 F.3d at 947.
[35] 175 Cal.App.4th at 642, 96 Cal. Rptr.3d at 121.
[36] 175 Cal.App.4th at 645, 96 Cal.Rptr.3d at 124.
[37] 175 Cal.App.4th at 636-637, 96 Cal.Rptr.3d at 117-118.

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