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JJE, Inc. dba Hospicio Toque de Amor
P.O. Box 1102
Manati, Puerto Rico 00674-1102

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SafeGuard Services LLC

CONFIDENTIAL

November 8, 2016

JJE, Inc. dba Hospicio Toque de Amor
P.O. Box 1102
Manati, Puerto Rico 00674-1102

RE: Medicare Payment Suspension
NPI: 1982819660
WMM #: 3103182016002

Dear JJE, Inc. dba Hospicio Toque de Amor:

This is to advise JJE, Inc. dba Hospicio Toque de Amor (hereinafter "JJE") that SafeGuard Services, LLC (hereinafter "SGS") is in receipt of JJE's rebuttal letter (hereinafter "The Rebuttal") dated October 6, 2016, in reference to the suspension of JJE's Medicare payments, which became effective on September 22, 2016. SGS received the Rebuttal on October 7, 2016 from Brian M. Daucher of the office of Sheppard, Mullin, Richter & Hampton LLP on behalf of JJE. After consideration of your Rebuttal, the Centers for Medicare & Medicaid Services (hereinafter "CMS") has determined that the suspension of JJE's Medicare payments will continue.

I. Introduction

In the Notice of Suspension of Medicare Payment (hereinafter "Suspension Notice") sent by SGS to JJE on September 23, 2016, SGS notified JJE that effective September 22, 2016, JJE's Medicare payments had been suspended for an initial period of up to 180 days. The suspension of JJE's Medicare payments was based, in part, on "reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination." See 42 C.F.R. § 405.371(a)(1). Here, an investigation conducted by SGS revealed that JJE was billing Medicare for hospice services for patients who were ineligible for such services under the Medicare Benefit because they did not meet Medicare criteria for terminal illness as evidenced by a life expectancy of six (6) months or less.

The Suspension Notice advised JJE of its right to submit a rebuttal statement, pursuant to 42 C.F.R. § 405.372(b)(2). Applicable regulations require CMS, or its contractor, to consider the

statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the termination of the suspension within fifteen (15) days of receipt. CMS provided an interim rebuttal response within fifteen (15) days, and this correspondence shall serve as CMS's official rebuttal response.

II. JJE's Rebuttal

JJE's Rebuttal claims that SGS failed to comply with the provisions of 42 U.S.C. § 1395ddd(f)(7). Specifically, JJE claims SGS failed to comply in the following ways:

a. Failed to give JJE adequate notice and request for audited charts ((f)(7)(A));
b. Failed to give JJE a full review and explanation of the findings;
c. Failed to give JJE an opportunity to provide additional information to SGS;
d. Failed to take into account information provided, on a timely basis, by JJE.

JJE claims that, pursuant to 42 U.S.C. § 1395ddd, CMS "is precluded from 'taking any action (or authoriz[ing] any other person, including any Medicare contractor...) to recoup the [alleged] overpayment until the date the decision on the reconsideration has been rendered.'"

In addition, JJE claims the payment suspension is improper because of specific statutory and regulatory authority. First, JJE claims that SGS authority to suspend payments is based upon "general" statutory mandate, which must yield to the specific statutory provision that payment suspensions may only be imposed in cases "where there is a credible allegation of fraud" pursuant to 42 U.S.C. § 1395y(o). Second, JJE claims that CMS is under an obligation to obtain permission from the Office of Inspector General in order to suspend payments based upon a credible allegation of fraud, citing to 76 F.R. 5929 (Feb. 2, 2011).

III. CMS Rebuttal Response

The payment suspension was implemented because an SGS investigation found that JJE submitted claims to Medicare for payment for hospice services provided to beneficiaries who did not qualify for hospice care under the Medicare Benefit because they did not meet Medicare criteria for terminal illness as evidenced by a life expectancy of six (6) months or less. To protect the integrity of the Medicare trust fund, CMS and SGS instituted the payment suspension without prior notice, as it was authorized to do, and has determined that the suspension should remain in place.

A. Prior Notice of the Payment Suspension was not Required

42 C.F.R. §§ 405.372(a)(3) and 405.372(b)(2) directly address the imposition of a payment suspension without prior notice to a provider. According to 42 C.F.R. §405.372(a)(3), "[a] suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money."

CMS and SGS have met the legal obligations imposed upon them in situations where prior notice of a payment suspension is not provided. 42 C.F.R.§405.372(b)(2) states that where "a suspension of payment is put into effect without prior notice to the provider or supplier, the Medicare contractor must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed." SGS advised JJE in the Suspension Notice that it "has the right to submit a Rebuttal Statement addressing why the payment suspension should be terminated."[1]

The section of the Program Integrity Manual cited in the Rebuttal regarding the suggested list of reasons for payment suspension without prior notice is not an exhaustive list. Program Integrity Manual section 8.3.2.2.1 sets forth a list of situations which provide for the mandatory imposition of a payment suspension without prior notice. The sections of the Code of Federal Regulations cited above provide the legal basis for CMS and SGS to impose a payment suspension without prior notice in other cases where the determination has been made that the Medicare Trust Funds may be harmed if advance notice were provided to the provider.

CMS and SGS have complied with relevant regulatory obligations concerning advance notice to JJE of the payment suspension.

B. The Payment Suspension is Supported by Relevant Statutes and Regulations

JJE claims that in instituting the suspension of JJE's Medicare payments, CMS violated *42 U.S.C. §1395ddd* in the following ways:

a. Failed to give JJE adequate notice and request for audited charts;
b. Failed to give JJE a full review and explanation of the findings;
c. Failed to give JJE an opportunity to provide additional information to SGS;
d. Failed to take into account information provided, on a timely basis, by JJE.

The portion of the United States Code section relied upon by JJE in its rebuttal, *42 U.S.C. §1395(f)*, is titled as follows:

> 42 U.S. Code § 1395ddd - Medicare Integrity Program
> (f) Recovery of overpayments

This section of the code describes the legal process to be followed to recover overpayments made by Medicare to providers. This, however, is not the legal process which CMS has instituted and is pursuing against JJE. Thus, this section does not apply and JJE's reliance upon its mandates is misplaced.

As stated in the Suspension Notice dated September 23, 2016, CMS has instituted against JJE a suspension of Medicare payments. A suspension is defined by regulation as the withholding of

[1] *JJE Notice of Suspension*; Pg. 4.

payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud. 42 C.F.R. § 405.370. It is a time-limited, temporary measure instituted to protect the Medicare Trust Funds while CMS and its contractors verify whether and how much payment was actually due the provider for past claims and ensure that if a provider was overpaid, sufficient funds are available to recover the overpayment. A suspension is accordingly distinct from a medical review, denial of claims, overpayment determination and recoupment. While prepayment and post payment medical review are usually performed in conjunction with a suspension, and may result in an overpayment determination and the recouping of funds, the suspension itself is only a "money hold." A provider can continue to render services during the suspension period as it normally would, and any payments made by Medicare during the suspension are held in escrow until the suspension has been terminated.

Once a suspension of payment is put into effect under 42 C.F.R. § 405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.[2] CMS or the Medicare contractor then informs the provider or supplier of any overpayment determination, which is subject to administrative and judicial review. See 42 U.S.C. § 1395ff; 42 C.F.R. Part 405, Subpart I. If CMS decides to initiate recoupment, which is defined by regulation as the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness, it sends notice of the recoupment to the provider. 42 C.F.R. § 405.370. The provider is offered an opportunity for rebuttal in accordance with 42 C.F.R. § 405.374, and recoupment is subject to certain limitations during the provider's appeal of the overpayment determination. 42 C.F.R. §§ 405.370; 405.379.

By contrast, a Medicare suspension is not defined as an initial determination subject to administrative and judicial review. See 42 C.F.R. § 405.375(c). In fact, for decades, courts have consistently dismissed actions for lack of subject matter jurisdiction that were commenced by providers to challenge Medicare suspensions and seek injunctive relief due to claims of irreparable harm. See e.g., MJG Management Assocs. v. NHIC Corp. et al., Case 13-1672 (1st Cir. Oct. 24, 2014) (Judgment affirming district court dismissal of case challenging Medicare suspension for lack of subject matter jurisdiction); Clarinda Home Health v. Shalala, 100 F.3d 526 (8th Cir. 1996); Cplace Springhill SNF v. Burwell, Civil Action No. 14-3139 (W.D. LA. April 21, 2015); Citadel Healthcare Services, Inc. v. Sebelius, Civil Action No. 3:10-CV-1077-BH, 2010 WL 5101389 (N.D. Tex. Dec. 8, 2010); Indeplus Group of Companies, Inc. v. Sebelius, Civil Action No. 3:10-CV-0557-O, 2010 WL 1372488 (N. D. Tex. April 7, 2010); Long Island Ambulance Inc. v. Thompson, 220 F.Supp.2d 150 (E.D.N.Y. 2002); Life Source Enterprises, Inc. v. Shalala, No. Civ.A.SA-00-CA-0902HG, 2000 WL 33348793 (W.D. Tex. Nov. 9, 2000); Diagnostic Cardioline Monitoring of New York, Inc., No. 99-CV-5685, 2000 WL 1132273 (E.D. N.Y. Jun. 26, 2000) (even upon a finding of irreparable harm, court denies

[2] Please be advised that in furtherance of this suspension protocol, we will be taking steps to determine the existence and size of any overpayment and will likely be requesting additional information, such as medical records and other supporting documentation, from JJE.

request for injunctive relief based upon lack of subject matter jurisdiction); Midwest Family Clinic, Inc. v. Shalala, 998 F.Supp. 763 (E.D. Mich. 1998); Neurological Assocs. v. Bowen, 658 F.Supp. 468 (S.D. Fla. 1987).

Therefore, the Rebuttal's contention that CMS has failed to comply with notice requirements and limitations on recoupment set forth in 42 U.S.C. § 1395ddd is entirely without merit, as CMS has merely suspended Medicare payments pending an overpayment determination. It has neither issued notice of a determined overpayment nor attempted to recover any such overpayment through recoupment.

C. CMS's Authority To Suspend Medicare Payments Is Not Limited To Cases Wherein There Are Credible Allegations Of Fraud

The Rebuttal further claims that pursuant to 42 U.S.C. § 1395y(o), CMS has the authority to "suspend ongoing payments to providers, but only where there was a 'credible allegation of fraud.'"[3] However, the language of this section does not support JJE's limited view of CMS's ability to suspend payments to providers. 42 U.S.C. § 1395y(o) reads as follows:

> Suspension of payments pending investigation of credible allegations of fraud
> (1) In general
> The Secretary may suspend payments to a provider of services or supplier under this subchapter pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

This statutory provision was enacted as part of the Patient Protection and Affordable Care Act of 2010, Pub., L. 111-148, and addresses suspensions in cases where there is a credible allegation of fraud. Specifically, the statutory provision requires the Secretary to consult with the Office of Inspector General in determining whether there is a credible allegation of fraud against a provider or supplier, and further provides that if a credible allegation of fraud exists, the Secretary may impose a suspension of payments pending an investigation of the allegations, unless the Secretary determines that there is good cause not to suspend payments. 42 U.S.C. § 1395y(o). Nowhere in this statute is there any language that even remotely supports the proposition that payment suspensions may be instituted only in cases where fraud is suspected.

In fact, CMS's regulations have authorized payment suspensions based upon reliable information that an overpayment exists since 1972. CMS's regulations were promulgated pursuant to rulemaking authority conferred by Congress on the Secretary. See 37 Fed. Reg. 10723 (May 27, 1972) (pointing to Section 1102 of the Social Security Act, which is codified at 42 U.S.C. § 1302; Section 1815, which is codified at 42 U.S.C. § 1395g; and Section 1871, which is codified at 42 U.S.C. § 1395hh); see also Midwest Family Clinic, Inc., 998 F. Supp. at 771 (suspension regulations appear to be within the Secretary's statutory authority, particularly under 42 U.S.C. § 1302(a), which provides the Secretary with authority to publish rules and regulations not

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[3] *JJE Rebuttal Letter*; page 4.

inconsistent with the Medicare statute, and 42 U.S.C. § 1395hh, which provides the Secretary with the authority to prescribe regulations to carry out the administration of the Medicare program); Neurological Assocs., 658 F.Supp. at 472 ("[t]he provisions of 42 C.F.R. Section 405.370-.373 were promulgated under the Secretary's general rule making authority").

CMS's regulation specifically authorizes a suspension of Medicare payments when there is reliable information that an overpayment exists. See 42 C.F.R. § 405.371. The regulation is found at 42 C.F.R. § 405.371(a) and reads as follows:

> (a) *General rules.* Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be -
> (1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination.

The Rebuttal also insinuates that CMS has failed to adhere to proper protocol in enacting the suspension. In support, the Rebuttal states that the dictates of 76 F.R. 5929 (Feb. 2, 2011) somehow preclude CMS from enacting the suspension. However, the language of this source expressly approves of the continued use of payment suspension, specifically in the case of overpayment:

> We believe that we must retain the ability to suspend payments in both cases of potential fraud and cases that do not involve potential fraud but are based solely on potential overpayments. We have long had the authority to suspend payments without evidence of fraud but historically have not often used the suspension tool in these cases. We will determine on a case-by-case basis whether a suspension of payments is appropriate in cases that do not involve fraud, and factors such as Medicare contractor claims processing errors and provider billing history are certainly considered.

As stated in the provider Suspension Notice, JJE's Medicare payments have been suspended because of "reliable information that an overpayment exists..." As payment suspensions for such determinations are supported by regulatory authority, CMS's suspension of JJE's payments is legally justified. In addition, CMS followed protocol in implementing the payment suspension. SGS conducted a thorough investigation, reported its findings as required, reached a deliberative decision to proceed with the suspension, and offered an opportunity for rebuttal.[4]

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[4] Furthermore, your assertion that CMS was required to consult with the Office of Inspector General is erroneous, because such consultations are only required when a suspension is based upon a credible allegation of fraud. See 42 C.F.R. § 405.371(a)(1); cf. 42 C.F.R. § 405.371(a)(2).

D. There Exists Reliable Information That An Overpayment Exists Or That Payments To Be Made May Not Be Correct

The suspension was implemented based upon reliable information obtained from SGS investigators that an overpayment exists, or that payments to be made may not be correct.

On July 20, 2016, an investigative team consisting of SGS investigators and a Registered Nurse conducted in-person interviews with Medicare beneficiaries for whom JJE submitted claims for hospice services to Medicare for payment. The investigative team determined the five (5) beneficiaries interviewed did not meet the eligibility criteria for terminal illness as outlined in the Medicare Benefit Policy Manual. See id. at Chapter 9, Section 10. See also Local Coverage Determination (LCD) L33393 and 42 C.F.R. § 418.

Based on observations and physical assessments made by the SGS investigative team and statements made by the beneficiaries and their caregivers during the interviews, the investigative team determined the five (5) Medicare beneficiaries did not meet Medicare criteria to qualify for hospice services. According to Local Coverage Determination (LCD) L33393, to qualify as terminally ill, a physician must certify that a patient's prognosis is a life expectancy of six (6) months or less if the terminal illness were to run its course. SGS investigators determined the five (5) beneficiaries interviewed did not have a life expectancy of six (6) months or less during the dates in which they received hospice services from JJE. All five (5) beneficiaries had stable medical conditions and were not experiencing a decline in their functional status.

Additionally, three (3) of the five (5) beneficiaries interviewed had a primary diagnosis of Alzheimer's disease upon admission to JJE. As noted in LCD L33393, there are certain criteria that must be met for a beneficiary suffering from Alzheimer's disease to qualify as terminally ill. Based on observations and physical assessments made by the SGS investigative team and statements made by the beneficiaries and their caregivers, the investigative team determined that one (1) of these beneficiaries did not meet the criteria listed in LCD 33393 required for patients suffering from Alzheimer's disease to qualify as terminally ill. The beneficiary did not meet the criteria for Stage 7 Alzheimer's disease and exhibited stable medical conditions with no continuing decline in clinical status.

The other two (2) of the beneficiaries interviewed who had a primary diagnosis of Alzheimer's disease upon admission to JJE were determined to meet the criteria for Stage 7 Alzheimer's disease. However, based on an assessment by the Registered Nurse, SGS determined the beneficiaries' medical conditions have remained stable and the beneficiaries do not have a life expectancy of six (6) months or less as required by Medicare regulations to qualify for hospice services.

The examples below are claims submitted by JJE to Medicare for payment for hospice services purportedly rendered to beneficiaries who did not meet Medicare criteria for terminal illness and/or Stage 7 Alzheimer's disease with a prognosis of a life expectancy of six (6) months or less during the dates of service for which JJE submitted claims for hospice services to Medicare on their behalf:

Claim Number	Claim From Date	Claim Thru Date	Basis for Selected Claim
	02/01/2016	02/29/2016	Beneficiary's diagnosis for hospice is Alzheimer's and under Medicare regulations, a beneficiary must meet the Stage 7 criteria to receive hospice services with a prognosis of a life expectancy of six (6) months or less. Beneficiary is a Stage 7 Alzheimer's patient whose medical condition has stabilized and beneficiary has not presented any medical complications or clinical decline in the past six (6) months. Beneficiary does not meet the Medicare criteria to receive hospice services as the beneficiary does not have a life expectancy of six (6) months or less.
	05/01/2016	05/31/2016	The beneficiary is not terminally ill and does not have a life expectancy of six (6) months or less. Beneficiary does not meet the Medicare criteria to receive hospice services.
	04/01/2016	04/30/2016	Beneficiary's diagnosis for hospice is Alzheimer's and under Medicare regulations, a beneficiary must meet the Stage 7 criteria to receive hospice services with a prognosis of a life expectancy of six (6) months or less. Beneficiary does not meet the Stage 7 Medicare requirements and does not qualify to receive hospice services.
	04/01/2016	04/30/2016	Beneficiary's diagnosis for hospice is Alzheimer's and under Medicare regulations, a beneficiary must meet the Stage 7 criteria to receive hospice services with a prognosis of a life expectancy of six (6) months or less. Beneficiary is an early Stage 7 Alzheimer's patient whose medical condition has stabilized and beneficiary has not presented any medical complications or clinical decline in the past six (6) months. Beneficiary does not meet the Medicare criteria to receive hospice services as the beneficiary does not have a life expectancy of six (6) months or less.
	04/01/2016	04/30/2016	The beneficiary is not terminally ill and does not have a life expectancy of six (6) months or

			less. Beneficiary does not meet the Medicare criteria to receive hospice services.

In addition, we note that the information contained in medical records reviewed to date supports the conclusion that the vast majority of the services/items reviewed are not payable under the Medicare program. In sum, we believe that the foregoing constitutes "reliable information" that an overpayment exists, or that payments to be made may not be correct, and therefore amply justify the suspension imposed.[5]

IV. Conclusion

After careful review of the information and evidence set forth in the Rebuttal, CMS concludes that the information provided fails to justify termination of the suspension of JJE's Medicare payments at this time.

If you have any questions, please contact SGS Scarlett Sevilla at our customer service number (954) 624-3999.

Sincerely,

Gary Portman, November 8, 2016

Gary Portman
Administrative Action Coordinator
SafeGuard Services, LLC - A CMS Zone Program Integrity Contractor
Medicare Integrity Program

cc: Sheppard Mullin Ritcher & Hampton LLP
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Attn: Brian M. Daucher

[5] Your reliance on U.S. ex rel. Wall v. Vista Hospice Care, Inc., 778 F. Supp.2d 709, 718 (N.D. Tex. 2011) and U.S. v. Asercare, Inc., 2:12-cv-00245 (3-31-2016 Order) to the contrary is misplaced. Both cases address liability under the False Claims Act, not the standard for implementing a Medicare suspension