



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



March 13, 2012

VIA ELECTRONIC MAIL

Sheila Sawyer, Esq.
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Church Street Health Management
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Nashville, TN 37219

Lorri Steiner
Chief Compliance Officer
Church Street Health Management
618 Church Street
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Nashville, TN 37219

RE: Notice of Material Breach and Intent to Exclude

Dear Ms. Sawyer and Ms. Steiner:

The purpose of this letter is to formalize the terms of an agreement between Church Street Health Management, formerly known as FORBA Holdings, LLC (hereinafter, "CSHM") and the Office of Inspector General (OIG) of the United States Department of Health and Human Services. This letter agreement specifies the general terms discussed by the OIG during our meeting on March 13, 2012.

As you are aware, the purpose of this meeting was to discuss CSHM's March 12, 2012 response to the OIG's Notice of Material Breach and Intent to Exclude (Notice) which was issued to CSHM on March 8, 2012 pursuant to the OIG's rights and authorities under the Corporate Integrity Agreement (CIA) executed between CSHM and the OIG. As we discussed during our meeting this morning, the OIG has determined that: (1) CSHM has cured certain breaches identified in the OIG's Notice; (2) the OIG is satisfied with CSHM's response to certain breaches that may not necessarily be cured at this time; and (3) CSHM has failed to satisfy the OIG that certain breaches identified in the OIG's Notice can or will be cured by CSHM within the requisite timeframe under the CIA. The OIG agrees not to proceed with an exclusion action for the specific breaches of the CIA identified in our Notice in exchange for CSHM's agreement to: (1) a voluntary exclusion of Small Smiles Dental Center of Manassas (Manassas Center) if CSHM fails to divest, transfer, and/or sell Manassas Center within 90 days; and (2) assume additional integrity-related obligations incorporated as an amendment to the CIA by this letter.

OIG's Determination that Certain Breaches are Cured

In our Notice, the OIG determined that CSHM was in material breach of its CIA for its failure to comply with the obligations of Sections III.I.2.c and III.I.2.d of the CIA. In its response to the Notice, CSHM has advised the OIG of its effort to cure this specific breach through its provision of written notice to the Virginia state licensing board of CSHM's investigation of issues at the Manassas Center. The OIG considers CSHM's response to have cured its breach of Sections III.I.2.c and III.I.2.d of the CIA.

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM's failure to comply with Section III.B.2.u of the CIA. In its response to the Notice, CSHM has advised the OIG of its effort to cure this specific breach through: (1) the revision of CSHM's policy entitled "Adverse Events, Quality of Care Reportable Events, and OMIG Patient Care Matters," and (2) CSHM's termination of the Covered Person identified in CSHM's September 26, 2011 Quality of Care Reportable Event Notice to the OIG. The OIG considers CSHM's actions described in its response to have cured its breach of Section III.B.2.u of the CIA.

OIG's Determination that CSHM's Response is Satisfactory with Respect to Breaches that Could not be Cured

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM's submission of a false certification under Section III.A.7 of the CIA. In its response to the Notice, CSHM indicated that it could not cure the breach of having submitted a false certification, but that the Certifying Employee who signed the false certification is no longer employed by CSHM. CSHM also indicated in its response to the Notice that it has "implemented significant training and revamped our process for

certifications” under the CIA and described many such actions. The OIG considers CSHM’s actions described in its response to be satisfactory with respect to the breach as cited under Section III.A.7 of the CIA.

OIG’s Determination that Certain Breaches have not been Cured or Cannot be Cured within the Requisite Timeframe

In our Notice, the OIG determined that CSHM was in material breach of its CIA for CSHM’s failure to comply with Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA. The OIG has reviewed CSHM’s March 12, 2012 response and determined that CSHM has failed to demonstrate to the OIG’s satisfaction that the breaches under Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA have been or will be cured within the requisite timeframe required by Section X.E.3 of CIA.

As we indicated in our meeting this morning, the OIG agrees not to pursue an exclusion action for CSHM’s breach of Sections III.B.2.d, III.B.2.g, and III.B.2.n of the CIA, as specifically addressed in our Notice, in exchange for CSHM’s agreement to: (1) a voluntary exclusion of Manassas Center within 90 days of the date of this letter; and (2) comply with additional integrity-related obligations that will be incorporated as an amendment to the CIA by this letter.

We understand that CSHM is in the process of closing or transferring the Manassas Center to an unrelated third party. In the event CSHM transfers the Manassas Center to an unrelated third party within 90 days of the date of this letter and CSHM has no affiliation or relationship with the new owner, the OIG would not pursue an exclusion of Manassas Center. In the event CSHM does not close or transfer The Manassas Center as described above, CSHM agrees that the Manassas Center shall be excluded from participation in the Federal health care programs.

The additional integrity-related obligations that the OIG will require are detailed as follows:

1. Compliance Program Onsite Reviews of CSHM Facilities. Within 30 days, CSHM shall develop and implement a process by which the Chief Dental Officer, the Compliance Officer, and Regional Dentists shall conduct at least one onsite review (“Onsite Review”) each month to a CSHM facility for the purpose of evaluating and ensuring compliance with all applicable Federal health care program requirements, state dental board requirements, and the obligations of the CIA. The OIG will require CSHM to recruit Regional Dentists who will assist with the Onsite Reviews as well as assisting the Chief Dental Officer with the review of patient care matters at CSHM and CSHM facilities, including but not limited to quality protocols, quality assessments, patient safety issues, utilization

review, performance improvement, and dental staff training. Regional Dentists will be required to maintain board-certification in pediatric dentistry and have experience treating pediatric Federal health care program beneficiaries. Within 30 days, CSHM shall prepare and submit to the OIG a plan to recruit Regional Dentists. The selection of CSHM facilities that will be subject to the Onsite Review should be based upon CSHM's evaluation of chart audit results, quality assurance indicators, CRAFT reports and complaints. Each Onsite Review shall include, at a minimum, the direct observation of patient care by the Chief Dental Officer and Regional Dentists, and an in-person review of CIA obligations by the Compliance Officer with the Lead Dentist and Compliance Liaison. Within 30 days after conducting an Onsite Review, the Chief Dental Officer and Compliance Officer shall prepare a written report of the onsite review ("Onsite Review Report") which shall provide details of the Onsite Review, and any findings, observations, and/or corrective action developed as a result of the Onsite Review. CSHM shall provide copies of all Onsite Review Reports to the OIG and the Independent Monitor.

2. Quality Improvement Initiatives. Within 30 days, CSHM shall develop and implement a process by which CSHM identifies specific risk areas and relevant quality benchmarks, taking into account the recommendations of the Independent Monitor, for the purpose of measuring and achieving quality improvement goals on an ongoing basis ("Quality Improvement Initiative"). The Quality Improvement Initiative shall be in addition to the current quality metrics maintained by CSHM. CSHM shall provide, on an ongoing basis, the identified risk areas and relevant quality benchmarks under the Quality Improvement Initiative to the OIG and the Independent Monitor.
3. Referral Process. Within 30 days, CSHM shall develop and implement guidance for each CSHM facility regarding patient referrals from CSHM facilities to other facilities better equipped to treat a patient in specific circumstances involving concerns for patient safety, including but not limited to anesthesia requirements, and behavior guidance techniques. Within 30 days, CSHM shall provide the OIG and the Independent Monitor with a listing of facilities to which referrals may be made for each CSHM facility. If no such referral-receiving facilities exist for any CSHM facility within the 30-day timeframe, CSHM shall provide the OIG and the Independent Monitor with an acceptable plan to identify or develop such facilities for those CSHM facilities.
4. Certifying Employee Certifications. Within 30 days, CSHM shall develop a specific process by which Certifying Employees shall perform a comprehensive assessment of the area under the Certifying Employee's supervision for purposes

of completing the Certifying Employee Certification process under Section III.A.7 of the CIA. The purpose of this requirement is to engage Certifying Employees in the process of evaluating and ensuring compliance with all applicable Federal health care program requirements, state dental board requirements, and the obligations of the CIA.

5. Pulp-to-Crown Medical Necessity Review. Within 120 days, CSHM will perform a review of claims documentation associated with CSHM dentists with high “pulp-to-crown” ratios to determine whether such documentation supports the medical necessity of the services (“Pulp-to-Crown Medical Necessity Review”). CSHM will adopt the appropriate ratio as determined by the Independent Monitor in order to identify all dentists who may be at risk for high “pulp-to-crown” utilization (“Reviewed Dentists”). CSHM will then perform the Pulp-to-Crown Medical Necessity Review for all claims submitted by or on behalf of the Reviewed Dentists from the Effective Date of the CIA to present. Within 150 days, CSHM shall prepare a Pulp-to-Crown Medical Necessity Review Report and provide copies to the OIG and the Independent Monitor. The Independent Monitor will perform a validation review of CSHM’s Pulp-to-Crown Medical Necessity Review. CSHM shall report to the OIG all overpayments determined by the Pulp-to-Crown Medical Necessity Review; further, CSHM agrees to refund within 30 days all overpayments determined by the Pulp-to-Crown Medical Necessity Review to the appropriate payors. CSHM will also be required to comply with all relevant provisions of the CIA as a result of findings under the Pulp-to-Crown Medical Necessity Review.

As we discussed, the OIG will instruct the Independent Monitor to carefully evaluate the extent to which CSHM has complied with its obligations under the CIA and, in particular, the additional CIA obligations that we outline in this letter.

The parties agree that this letter shall serve as an amendment to the CIA and that CSHM’s failure to implement the additional integrity obligations set forth in this letter shall be a Material Breach under Section X.E.1 and shall be subject to Stipulated Penalties under Section X.B.1 of the CIA. The parties agree that the OIG has relied upon the representations of CSHM in its March 12, 2012 letter. In the event that the OIG determines CSHM’s representations were not accurate, the OIG may reinstate its Notice and pursue an exclusion of CSHM.

If CSHM agrees to the terms of this letter, please provide the countersignatures below and return this letter no later than Wednesday, March 14, 2012. If you have any questions regarding this letter or CSHM's obligations under its CIA, please contact Felicia Heimer at (305) 536-6927.

Sincerely,

/Robert K. DeConti/ Acting for
Gregory E. Demske
Assistant Inspector General for Legal Affairs

/Sheila W. Sawyer/
Sheila Sawyer, Esq.
General Counsel, Chief Administrative Officer
Church Street Health Management

3/14/2012
Date

/Lorri L. Steiner/
Lorri Steiner
Senior Vice President, Chief Compliance Officer
Church Street Health Management

3/14/2012
Date