



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



MAR 07 2014

VIA UPS and Electronic Mail

Danette Manzi
Chief Compliance Officer
CSHM, LLC
618 Church Street
Suite 520
Nashville, TN 37219

Re: Exclusion of CSHM, LLC

Dear Ms. Manzi:

This Exclusion Letter is to notify CSHM, LLC (CSHM) that it is being excluded from participation in Medicare, Medicaid, and all Federal health care programs as defined in section 1128(B)(f) of the Social Security Act for a minimum period of five years. This action is being taken pursuant to the Breach and Default Provisions of the Corporate Integrity Agreement (CIA) between CSHM and the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). OIG is issuing this Exclusion Letter pursuant to Section X.E.4 of the CIA, based on CSHM's material breaches of the CIA and its failure to cure those breaches.

Basis for Exclusion

OIG issued Notices of Material Breach and Intent to Exclude to CSHM on December 6, 2013, and January 7, 2014 (Notices). Pursuant to Section X.E.3 of the CIA, CSHM had 30 days from the date of its receipt of the Notices to cure the material breaches by demonstrating to OIG's satisfaction that:

1. CSHM was in compliance with the obligations cited by OIG as the basis for the material breaches;
2. The alleged material breaches had been cured; or
3. The alleged material breaches could not be cured within the 30-day period, but that: (a) CSHM had begun to take action to cure the material breaches; (b) CSHM was pursuing such action with due diligence; and (c) CSHM had provided a reasonable timetable to cure the material breaches.

On January 15, 2014, CSHM submitted its response to the Notices. OIG held a meeting with CSHM on February 12, 2014. OIG has considered all of the information CSHM furnished to OIG in response to the Notices. OIG concludes that CSHM has failed to satisfy the requirements of Section X.E.3 of the CIA to cure its material breaches of the CIA.

OIG finds that CSHM is in material breach of the CIA based on the following separate and independent material breaches of the CIA. As of the date of this letter, these material breaches have not been cured. Each independent material breach of the CIA listed below is an independent basis for the imposition of an exclusion pursuant to Section X.E.4 of the CIA.

1. CSHM failed to report a Quality of Care Reportable Event as required by Section III.I.2.d of the CIA. This event involved Patient (b)(6) and occurred at Children's Dental Clinic of Tulsa, PLLC d/b/a Oklahoma Smiles Dental Centers of Tulsa in Tulsa, Oklahoma (Oklahoma Smiles). The failure by CSHM to report a Quality of Care Reportable Event, take corrective action to OIG's satisfaction, and make appropriate notifications, as required by Section III.I.2.c-d, is a material breach of the CIA under Section X.E.1.b.
2. CSHM failed to report a Quality of Care Reportable Event as required by Section III.I.2.d of the CIA. This event involved Patient (b)(6) and occurred at Small Smiles of Mattapan, LLC d/b/a Small Smiles Dental Centers of Mattapan in Mattapan, Massachusetts. The failure by CSHM to report a Quality of Care Reportable Event, take corrective action to OIG's satisfaction, and make appropriate notifications, as required by Section III.I.2.c-d, is a material breach of the CIA under Section X.E.1.b.
3. CSHM failed to maintain a disclosure log that meets the requirements of Section III.F of the CIA. CSHM failed to include the disclosure regarding Dentist (b)(6) at Oklahoma Smiles on the disclosure log. Further, CSHM failed to include the Quality of Care Reportable Event involving Patient (b)(6) on the disclosure log. CSHM also failed to include the Chief Dental Officer's October 22, 2013 disclosure to the Chief Compliance Officer on the disclosure log. The failure to maintain a disclosure log that meets the requirements of Section III.F is a material breach of the CIA under Section X.E.1.c.
4. CSHM failed to implement a policy and procedure to develop a mechanism for informing all current patients, parents, and guardians who received care from a CSHM facility when a substantiated incident of patient harm occurs

at that CSHM facility as required by Section III.B.2.m of the CIA. The failure to implement this policy and procedure is a material breach of the CIA under Section X.E.1.h.

5. CSHM failed to comply with the Compliance Program Onsite Review of CSHM Facilities requirement of the March 2012 Amendment to the CIA by failing to have, at a minimum, the Chief Dental Officer, Regional Dentist, and Chief Compliance Officer participate in each compliance program onsite review visit to a CSHM facility. The failure to comply with the Compliance Program Onsite Review of CSHM Facilities requirement is a material breach of the CIA under Section X.E.1.c.
6. CSHM failed to perform annual General Training in the Third Reporting Period as required by Section III.C.1 of the CIA. The failure to comply with the General Training requirement is a material breach of the CIA under Section X.E.1.c.
7. CSHM failed to comply with the Compliance Officer Certification requirement of Section V.C.2 of the CIA. On March 14, 2013, CSHM submitted a false certification by the Chief Compliance Officer with its Third Annual Report to OIG. The submission of a false certification by CSHM is a material breach of the CIA under Section X.E.1.g.

Therefore, OIG is excluding CSHM from participation in Federal health care programs pursuant to Section X.E.4 of the CIA.

The Effect of Exclusion

The exclusion described in this letter is from participation in Medicare, Medicaid, and all Federal health care programs, as defined in section 1128B(f) of the Act, 42 U.S.C. § 1320a-7b(f). The effect of the exclusion is that no program payment will be made for any items or services furnished by CSHM, except as provided in regulations found at 42 C.F.R. § 1001.1901(c), during the period in which the company is excluded. Such exclusion shall have national effect. CSHM shall not submit or cause to be submitted to any Federal health care program a claim or request for payment for items or services, including administrative and management services, furnished during the exclusion. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion.

Reinstatement is not automatic. If at the end of the period of exclusion, CSHM wishes to apply for reinstatement, CSHM must submit a written request for reinstatement under the procedures set forth in Section X.E.4 of the CIA.

Appeal Rights

The exclusion described in this letter is effective 30 days from the date of this letter unless CSHM submits a request for a hearing within 25 days of receipt of this letter.

To request a hearing, CSHM must file a written request under the procedures set forth at Section X.F of the CIA. Specifically, OIG's determination to exclude CSHM shall be subject to review by an HHS Administrative Law Judge and, in the event of an appeal, the HHS Departmental Appeals Board, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21.

CSHM's request for hearing should be filed with the Departmental Appeals Board electronic filing system website (DAB E-File) at <https://dab.efile.hhs.gov>. To file a new appeal using DAB E-File, CSHM must first register a new account, by: (1) clicking "Register" on the DAB E-File home page; (2) entering the information requested on the "Register New Account" form; then (3) clicking "Register Account" at the bottom of the form. If CSHM has more than one representative, each representative must register separately to use DAB E-File on CSHM's behalf.

The e-mail address and password provided during registration must be entered on the login screen <https://dab.efile.hhs.gov/login> to access DAB E-File. A Registered User's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative. Once registered, you may file your appeal by:

- Clicking the "File New Appeal" link on the "Manage Existing Appeals" screen, then clicking "Civil Remedies Division" on the "File New Appeal" screen; and
- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in Portable Document Format (PDF). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. Eastern Standard Time of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that OIG files, or CRD issues on behalf of the Administrative Law Judge, via DAB E-File. Correspondingly, OIG also will be deemed to have consented to electronic service. More detailed instructions on

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DAB E-File for CRD cases can be found on the link to CRD E-File Procedures on the File New Appeal Screen for CRD appeals.

In the event CSHM is unable to file a hearing request using the DAB E-File system, CSHM may submit all of the required information by mail to:

Karen Robinson, Esquire
Director, Civil Remedies Division
Departmental Appeals Board, MS 6132
330 Independence Avenue, SW
Cohen Building, Room G-644
Washington, D.C. 20201
Telephone: (202) 565-0110

Failure to timely exercise your rights to a hearing shall make the exclusion final. If you have any questions concerning this letter, please have your attorney contact Tamara Forsys at (202) 205-2997, Maame Gyamfi at (202) 205-9493, or Robert Penezic at (202) 205-3211.

Sincerely,



Robert K. DeConti
Assistant Inspector General for Legal Affairs