

**FIRST AMENDMENT TO THE
CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEADOWS REGIONAL MEDICAL CENTER, INC.**

I. PREAMBLE

Meadows Regional Medical Center, Inc. (Meadows) and the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) that was executed by and between Meadows and OIG and that became effective on November 16, 2017. Contemporaneously with this Amendment, Meadows is entering into a Settlement Agreement with the United States.

Pursuant to Section XI.B of the CIA, the CIA may not be amended except by written consent of the parties to the CIA. Meadows and OIG hereby agree that the CIA between Meadows and OIG shall be amended as described below in this Amendment.

II. AMENDMENTS

A. The period of the compliance obligations assumed by Meadows under the Amendment shall begin on the date the final signatory signs this Amendment (Amendment Effective Date).

B. The Focus Arrangements Review provisions outlined in Section III.D. of the CIA and Appendix B of the CIA shall remain in effect through the original five-year period of the CIA, which was effective on November 16, 2017.

C. The following paragraph shall be added after Section III.A.3.c:

d. for each Reporting Period of the CIA following the Amendment Effective Date, the Board shall retain an individual or entity with expertise in compliance with Federal health care program

requirements (Compliance Expert) to perform a review of the effectiveness of Meadows' Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Meadows' compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Meadows' compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Meadows. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

D. Section III.E of the CIA is amended to add the following paragraph after section III.E.1.a.:

- i. *Engagement of Independent Review Organization for Claims Review.* Within 90 days after the Amendment Effective Date, Meadows shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Claims Review IRO"), to perform the reviews listed in Section III.E.4. The applicable requirements relating to the Claims Review IRO are outlined in Appendix C to this CIA, which is incorporated by reference.

E. Section III.E of the CIA is amended to add the following paragraph after section III.E.2. and to thereafter re-designate section III.E.3 as III.E.4:

3. *Claims Review.* The Claims Review IRO shall review claims submitted by Meadows and reimbursed by the Medicare and Medicaid programs, to determine whether the items or services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare an Claims Review Report, as outlined in Appendix D of the Amendment to the CIA, which is incorporated by reference. The Claims Review IRO must comply with the Independence and Objectivity Certification requirements of Section III.E.4 of the CIA.

F. Section V.A of the CIA (Implementation Report) is amended to add the following paragraph after Section V.A.15:

16. Meadows has previously submitted a written report to OIG summarizing the status of its implementation of the requirements of the CIA effective on November 16, 2017. Within 120 days after the Amendment Effective Date, Meadows shall submit a written report to OIG summarizing the status of its implementation of the additional requirements of this Amendment (Amendment Implementation Report). The Amendment Implementation Report shall include:

- a. the following information regarding the Claims Review IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the Claims Review IRO has the qualifications outlined in Appendix C to this CIA; and (d) a certification from the Claims Review IRO regarding its professional independence and objectivity with respect to Meadows that includes a summary of all current and prior engagements between Meadows and the Claims Review IRO;
- b. a list of all Policies and Procedures not previously provided that relate to Meadows' compliance with Federal health care program requirements for coding, billing, and claims submission for wound care services (copies of the Policies and Procedures shall be made available to OIG upon request); and
- c. a certification from the Compliance Officer that (1) to the best of his or her knowledge, Meadows is in compliance with all of the requirements of this Amendment; and (2) he or she has reviewed the Amendment Implementation Report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

G. Section V.B.3 of the CIA (Annual Reports) is amended to read as follows:

the Compliance Program Review Report and the Board resolution required

by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

H. Section V.B.8 of the CIA (Annual Reports) is amended to read as follows:

A certification from the IRO and from the Claims Review IRO regarding each IRO's professional independence and objectivity with respect to Meadows, including a summary of all current and prior engagements between Meadows and the IRO or Claims Review IRO.

I. Section X.A.2 through X.A.7 are removed from the CIA and replaced with the following:

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Meadows fails to engage and use an IRO or a Claims Review IRO, as required by Section III.E, Appendices A, B, C or D.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Meadows fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Meadows fails to submit any Arrangement Review Report or Claims Review Report in accordance with the requirements of Section III.E and Appendices B or D or fails to repay any Overpayment identified by the Claims Review IRO, as required by Appendix D.

5. A Stipulated Penalty of \$2,500 for each day Meadows fails to grant access as required in Section VII (This Stipulated Penalty shall begin to accrue on the date Meadows fails to grant access.).

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Meadows as part of its Implementation Report, Amendment

Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day Meadows fails to grant the IRO or Claims Review IRO access to all records and personnel necessary to complete the reviews listed in Section E, and for each day Meadows fails to furnish accurate and complete records to the Claims Review IRO, as required by Section III.E and Appendix C.

8. A Stipulated Penalty of \$1,000 for each day Meadows fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Meadows stating the specific grounds for its determination that Meadows has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Meadows shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Meadows receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

III. EFFECTIVE AND BINDING AGREEMENT

A. All terms and conditions of the CIA and in this Amendment shall remain in effect for five years after the CIA Effective Date.

B. The undersigned Meadows signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatories represent that they are signing this Amendment in their official capacities and that they are authorized to execute this Amendment.

C. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.

ON BEHALF OF MEADOWS REGIONAL MEDICAL CENTER, INC.

/J. Alan Kent/

10/29/19

J. ALAN KENT
President and Chief Executive Officer
Meadows Regional Medical Center, Inc.

DATE

/Chesley S. McLeod/

10/29/19

CHESLEY S. MCLEOD
Counsel for Meadows Regional Medical Center, Inc.

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/

10/25/2019

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Sarah Kessler/

10/30/2019

SARAH KESSLER
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX C

CLAIMS REVIEW INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Claims Review Independent Review Organization (Claims Review IRO) required by the First Amendment to the CIA.

A. Claims Review IRO Engagement

1. Meadows shall engage a Claims Review IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The Claims Review IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.16 of the CIA or any additional information submitted by Meadows in response to a request by OIG, whichever is later, OIG will notify Meadows if the Claims Review IRO is unacceptable. Absent notification from OIG that the Claims Review IRO is unacceptable, Meadows may continue to engage the Claims Review IRO.

2. If Meadows engages a new Claims Review IRO during the term of the First Amendment to the CIA, that Claims Review IRO must also meet the requirements of this Appendix. If a new Claims Review IRO is engaged, Meadows shall submit the information identified in Section V.A.16.a of the CIA to OIG within 30 days of engagement of the Claims Review IRO. Within 30 days after OIG receives this information or any additional information submitted by Meadows at the request of OIG, whichever is later, OIG will notify Meadows if the Claims Review IRO is unacceptable. Absent notification from OIG that the Claims Review IRO is unacceptable, Meadows may continue to engage the Claims Review IRO.

B. Claims Review IRO Qualifications

The Claims Review IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. Claims Review IRO Responsibilities

The Claims Review IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Claims Review;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation;

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix D to the CIA.

D. Meadows Responsibilities

Meadows shall ensure that the Claims Review IRO has access to all records and personnel necessary to complete the reviews listed in III.E of this CIA and that all records furnished to the Claims Review IRO are accurate and complete.

E. Claims Review IRO Independence and Objectivity

The Claims Review IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. Claims Review IRO Removal/Termination

1. *Meadows and Claims Review IRO.* If Meadows terminates its Claims Review IRO or if the Claims Review IRO withdraws from the engagement during the term of the CIA, Meadows must submit a notice explaining (a) its reasons for termination of the Claims Review IRO or (b) the Claims Review IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Meadows must engage a new Claims Review IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the Claims Review IRO.

2. *OIG Removal of Claims Review IRO.* In the event OIG has reason to believe the Claims Review IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Meadows in writing regarding OIG's basis for determining that the Claims Review IRO has not met the requirements of this Appendix. Meadows shall have 30 days from the date of OIG's written notice to provide information regarding the Claims Review IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Meadows regarding the Claims Review IRO, OIG determines that the Claims Review IRO has not met the requirements of this Appendix, OIG shall notify Meadows in writing that Meadows shall be required to engage a new Claims Review IRO in accordance with Paragraph A of this Appendix. Meadows must engage a new Claims Review IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Meadows to engage a new Claims Review IRO shall be made at the sole discretion of OIG.

APPENDIX D

CLAIMS REVIEW

A. Claims Review. The Claims Review IRO shall perform the Claims Review annually to cover each of the three remaining Reporting Periods. The Claims Review IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money Meadows has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the Claims Review IRO in connection with the Claims Review performed under this Appendix D.
- b. Paid Claim: A claim submitted by Meadows and for which Meadows has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Meadows and the Claims Review IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period.

Meadows, or its Claims Review IRO on behalf of Meadows, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by Meadows or its Claims Review IRO or (2) information furnished to OIG regarding the results of Meadows' internal risk assessment and internal auditing. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

2. *Claims Review Sample*. The Claims Review IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Meadows' office or under Meadows' control and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claim was correctly coded, submitted, and

reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the Claims Review IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The Claims Review IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

3. *Other Requirements.*

- a. Supplemental Materials. The Claims Review IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and Meadows shall furnish such documentation and materials to the Claims Review IRO prior to the Claims Review IRO initiating its review of the Claims Review Sample. If the Claims Review IRO accepts any supplemental documentation or materials from Meadows after the Claims Review IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the Claims Review IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the Claims Review IRO gave to the Supplemental Materials in its review. In addition, the Claims Review IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the Claims Review IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Meadows cannot produce documentation shall be considered an error and the total reimbursement received by Meadows for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

4. *Repayment of Identified Overpayments.* Meadows shall repay within 60 days any Overpayment(s) identified by the Claims Review IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare & Medicaid Services (CMS) guidance

(the “CMS overpayment rule”). If Meadows determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Meadows shall repay that amount at the mean point estimate as calculated by the Claims Review IRO. Meadows shall make available to OIG all documentation that reflects the refund of any Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from Meadows to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

B. Claims Review Report. The Claims Review IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*
 - a. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the Claims Review IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.3.a., above.
2. *Statistical Sampling Documentation.*
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the Claims Review IRO.
 - b. A description or identification of the statistical sampling software package used by the Claims Review IRO.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of Meadows' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A description of controls in place at Meadows to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.
- iii. A narrative explanation of the Claims Review IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.

b. Quantitative Results.

- i. Total number and percentage of instances in which the Claims Review IRO determined that the coding of the Paid Claims submitted by Meadows differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Meadows.
- ii. Total number and percentage of instances in which the Claims Review IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to Meadows.
- iii. Total number and percentage of instances in which the Claims Review IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Meadows.
- iv. Total dollar amount of all Overpayments in the Claims Review Sample.
- v. Total dollar amount of Paid Claims included in the Claims Review Sample.
- vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the

Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.

- vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
- viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the Claims Review IRO), correct allowed amount (as determined by the Claims Review IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

- c. Recommendations. The Claims Review IRO's report shall include any recommendations for improvements to Meadows' billing and coding system or to Meadows' controls for ensuring that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.