

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NOSHEEN HASAN, M.D. AND
CENTER FOR PAIN MANAGEMENT, S.C.**

I. PREAMBLE

Nosheen Hasan, M.D. (Dr. Hasan) and Center for Pain Management, S.C. (the Center) (Dr. Hasan and the Center are referred to collectively as “Center for Pain Management”) hereby enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, Dr. Hasan and the Center are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Center for Pain Management’s final annual report; or (2) any additional materials submitted by Center for Pain Management pursuant to OIG’s request, whichever is later.

C. The term “Covered Persons” includes:

1. Dr. Hasan and all employees of Dr. Hasan, and all owners and employees of the Center; and

2. all contractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of Center for Pain Management shall not be considered Covered Persons, provided that Center for Pain Management and the third party billing company provide the certifications required by Section III.J) on behalf of Center for Pain Management.

3. “Ordering Provider” means any Covered Person physician or non-physician practitioner who orders urine drug tests.

III. INTEGRITY OBLIGATIONS

Center for Pain Management shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer

1. *Compliance Officer.* Within 90 days after the Effective Date, Center for Pain Management shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be an employee and a member of senior management of Center for Pain Management, shall report directly to the Owner or Chief Executive Officer of Center for Pain Management, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Center for Pain Management. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this IA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters to the Owner or Chief Executive Officer of Center for Pain Management and shall be authorized to report on such matters to the Owner or Chief Executive Officer at any time. Written documentation of the Compliance Officer’s reports to the Owner or Chief

Executive Officer shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Center for Pain Management as well as any reporting obligations created under this IA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this IA.

Center for Pain Management shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this IA, within five business days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, Center for Pain Management shall develop and implement written policies and procedures regarding appropriate billing, medical record documentation, the operation of its compliance program, including the compliance program requirements outlined in this IA, and Center for Pain Management's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the Stark Law, and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law);
- c. the Federal health care program requirements regarding the accurate submission of claims for items or services. Specifically, Center for Pain Management shall develop and implement Policies and Procedures designed to:

- i. prevent Center for Pain Management from submitting claims for items and services that are not medically reasonable and necessary given the patient's clinical condition, including a requirement that all orders for items or services must include diagnostic and other information sufficient to support the medical necessity of each item or service ordered; and
 - ii. prevent Center for Pain Management from submitting claims for items and services that are not covered services by the applicable Federal health care program to which the claim is being submitted. Such Policies and Procedures shall comply with all National Coverage Determinations, Local Coverage Determinations, manual provisions, and any other guidance, issued either publicly or directly to Center for Pain Management, by any Federal or State payor.
- d. disciplinary policies and procedures, including corrective action plans as appropriate, for violations of Center for Pain Management's Policies and Procedures.

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this IA, Center for Pain Management shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), Center for Pain Management shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Posting of Notice

Within 60 days after the Effective Date, Center for Pain Management shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Officer and the HHS OIG Fraud Hotline

telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education

1. *Covered Persons Training.* All Covered Persons shall receive at least three hours of training during the first Reporting Period. Training may be completed in-person or online. These training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), Center for Pain Management's Medicare contractor, or other training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

- a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives relating to the items or services furnished by Center for Pain Management;
- b. the Federal health care program medical record documentation requirements relating to items or services furnished by Center for Pain Management; and
- c. the personal obligation of each individual involved in the medical record documentation and claim submission processes to ensure that medical records and claims are accurate; and
- d. the requirements of 42 U.S.C. §1320a-7b(b) (the Anti-Kickback Statute) and 42 U.S.C. §1395nn (the Stark Law), the legal sanctions under the Anti-Kickback Statute and the Stark Law, and examples of violations of the Anti-Kickback Statute and the Stark Law.

New Covered Persons shall receive at least three hours of training within 90 days after becoming a Covered Person.

The OIG may, in its discretion, require that Dr. Hasan or all Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to Center for Pain Management of such additional required training at least 180 days prior to the required completion date for such training.

2. *Ordering Providers Training.* All Ordering Providers shall receive training during each Reporting Period regarding the Federal health care program requirements relating to: (i) the medical reasonableness and necessity of urine drug testing based on the patient’s clinical condition and risk level; (ii) the relevance of the testing results; and (iii) application of the results in patient treatment.

3. *Training Records.* Center for Pain Management shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons and Ordering Providers required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 60 days after the Effective Date, Center for Pain Management shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Center for Pain Management shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Center for Pain Management) related to the reviews.

- c. *Access to Records and Personnel.* Center for Pain Management shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Claims Review.* The IRO shall conduct a review of Center for Pain Management's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether (a) the items and services furnished were medically necessary and appropriately documented, and whether the claims were correctly coded, submitted, and reimbursed; and (b) whether any diagnostic testing ordered was medically reasonable and necessary, for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

3. *Independence and Objectivity Certification.* Prior to performing the first Quarterly Claims Review, and annually thereafter, the IRO shall submit to Center for Pain Management a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA. The IRO's certification shall include a summary of all current and prior engagements between Center for Pain Management and the IRO.

F. Ineligible Persons

1. *Definitions.* For purposes of this IA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or

- ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Center for Pain Management shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Center for Pain Management shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Center for Pain Management shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.
- c. Center for Pain Management shall require all Covered Persons to disclose immediately if they become an Ineligible Person.

Center for Pain Management shall maintain documentation (i.e., a print screen of the search results) in order to demonstrate that Center for Pain Management: (1) has checked the Exclusion List and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.F affects Center for Pain Management's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Center for Pain Management understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Center for Pain Management may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Center for Pain Management meets the requirements of Section III.F.

3. *Removal Requirement.* If Center for Pain Management has actual notice that a Covered Person has become an Ineligible Person, Center for Pain Management shall remove such Covered Person from responsibility for, or involvement with, Center for Pain Management's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Center for Pain Management has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Center for Pain Management shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Center for Pain Management shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Center for Pain Management conducted or brought by a governmental entity or its agents involving an

allegation that Center for Pain Management has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Center for Pain Management shall also provide written notice to OIG within 30 days after the resolution of the matter and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

H. Overpayments

1. *Definition of Overpayments.* An “Overpayment” means any funds that Center for Pain Management receives or retains under any Federal health care program to which Center for Pain Management, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Repayment of Overpayments.* If, at any time, Center for Pain Management identifies any Overpayment, Center for Pain Management shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) in accordance with 42 U.S.C. § 1320a-7k(d) and any applicable regulations and guidance from the Centers for Medicare and Medicaid Services (CMS). Center for Pain Management should follow the payor’s policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

1. *Definition of Reportable Event.* For purposes of this IA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

- d. the filing of a bankruptcy petition by Center for Pain Management.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Center for Pain Management determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Center for Pain Management shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a and III.I.1.b.* For Reportable Events under Section III.I.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Center for Pain Management to identify and quantify any Overpayments; and
- e. a description of Center for Pain Management's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Center for Pain Management shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable

regulations and CMS guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;
- c. a description of the Exclusion List screening that Center for Pain Management completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Center for Pain Management to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Center for Pain Management identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Center for Pain Management is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA Center for Pain Management contracts with a third party billing company to submit claims to the Federal health care programs on behalf of Center for Pain Management, Dr. Hasan and the Center must certify to OIG that she/it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company.

Center for Pain Management also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the Exclusion List; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in Center for Pain Management's Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Sales or Purchase of a Location or Business

In the event that, after the Effective Date, Dr. Hasan or the Center proposes to (a) sell any or all of her or its locations or businesses that are subject to this IA (whether through a sale of assets, a sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. Dr. Hasan or the Center (as applicable) shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, Dr. Hasan or the Center wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, Dr. Hasan or the Center (as applicable) must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the proposed purchaser.

B. New Employment or Contractual Arrangement

At least 30 days prior to Dr. Hasan becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Dr. Hasan shall notify OIG of her plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of Dr. Hasan's responsibilities with respect to such potential employer or contractor. In addition, prior to Dr. Hasan becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by any Federal health care program, Dr. Hasan shall notify that party of this IA. This notification shall include a copy of the IA and a statement indicating the remaining term of the IA. The IA shall continue to apply to Dr. Hasan following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. **IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS**

A. Implementation Report

Within 90 days after the Effective Date, Center for Pain Management shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. a list of the Policies and Procedures required by Section III.B.;

3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

4. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Center for Pain Management that includes a summary of all current and prior engagements between Center for Pain Management and the IRO;

5. a copy of the search result print screens demonstrating that Center for Pain Management has screened all Covered Persons against the Exclusion List, as required by Section III.F, within 30 days of the Effective Date;

6. a copy of any certifications from Center for Pain Management and the third-party billing company required by Section III.J (if applicable);

7. a list of all of Center for Pain Management's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s), and/or supplier number(s); and

8. a certification by the Compliance Officer and Dr. Hasan that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Center for Pain Management is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

B. IRO Claims Review Reports

Within 60 days following the end of each three-month period during the term of this IA, Center for Pain Management shall provide to OIG a copy of the Quarterly Claims Review Report prepared by the IRO for each Quarterly Claims Review performed, along with Center for Pain Management's response and corrective action plan related to any recommendations made by the IRO, including Center for Pain Management's determination of whether the CMS overpayment rule requires the repayment of an

extrapolated Overpayment (as defined in Appendix B), in the Quarterly Claims Review Report. Each Quarterly Claims Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports

Center for Pain Management shall submit to OIG a report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall, at a minimum, include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;
2. a list of any new or revised Policies and Procedures developed during the Reporting Period;
3. the following information regarding the Covered Persons training required by Section III.D during the first reporting period (and any additional hours of training required for the second and third reporting periods): a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;
4. the following information regarding the Ordering Providers training required by Section III.D: a copy of the training program registration for each Ordering Provider who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program. A copy of all training materials shall be made available to OIG upon request;
5. a complete copy of all reports prepared pursuant to Section III.E and Center for Pain Management's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

6. a certification from the IRO regarding its professional independence and objectivity with respect to Center for Pain Management, including a summary of all current and prior engagements between Center for Pain Management and the IRO;

7. a copy of the search result print screens demonstrating that Center for Pain Management screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.F;

8. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

9. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

10. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

11. a copy of any certifications from Dr. Hasan, the Center and the third-party billing company required by Section III.J (if applicable);

12. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Center for Pain Management's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

13. a description of all changes to the most recently provided list of Center for Pain Management's locations (including addresses) as required by Section V.A.7;

14. a certification signed by the Compliance Officer and Dr. Hasan that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, Center for Pain Management is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Annual

Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and (d) he or she understands that the certification is being provided to and relied upon by the United States; and

15. a certification signed by Dr. Hasan that (a) prior to Dr. Hasan or the Center entering into or renewing any arrangement, transaction, or relationship that may implicate the Anti-Kickback Statute or Stark Law, such arrangement, transaction, or relationship has been subject to review by counsel with expertise in the Anti-Kickback Statute and the Stark Law; (b) any remuneration (i.e., anything of value) provided or received by Dr. Hasan or the Center in connection with any arrangement, transaction, or relationship that implicates the Anti-Kickback Statute or Stark Law complies with the financial terms of the arrangement, transaction, or relationship; (c) to the best of her knowledge, Dr. Hasan and the Center have not violated the Anti-Kickback Statute or Stark Law during the Reporting Period; and (d) she understands that this certification is being provided to and relied upon by the United States. If Dr. Hasan is unable to provide such a certification, she shall provide a written explanation of the reasons why she is unable to provide the certification. Documentation relating to Dr. Hasan and the Center's compliance with the requirements of this certification shall be made available to OIG upon request.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

D. Designation of Information

Center for Pain Management shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Center for Pain Management shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this IA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Center for Pain Management
Anne Wagner
6200 W. Center Street
Milwaukee, WI 53210
Telephone: (414) 444-8670
Facsimile: (414) 444-8678
Email: awagner@painwellnessexperts.com

Unless otherwise specified, all notifications and reports required by this IA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Center for Pain Management may be required to provide OIG with an additional copy of each notification or report required by this IA in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine or request copies of Center for Pain Management's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Center for Pain Management's locations for the purpose of verifying and evaluating: (a) Center for Pain Management's compliance with the terms of this IA and (b) Center for Pain Management's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Center for Pain Management to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview Center for Pain Management and

any of Center for Pain Management's owner, employees, and contractors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Center for Pain Management shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Center for Pain Management's employees and contractors may elect to be interviewed with or without a representative of Center for Pain Management present.

VIII. DOCUMENT AND RECORD RETENTION

Center for Pain Management shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Center for Pain Management prior to any release by OIG of information submitted by Center for Pain Management pursuant to its obligations under this IA and identified upon submission by Center for Pain Management as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Center for Pain Management shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

Center for Pain Management is expected to fully and timely comply with all of its IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Center for Pain Management and OIG hereby agree that failure to comply with certain obligations set forth in this IA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day Center for Pain

Management fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. appoint a Compliance Officer as required by Section III.A;
- b. written Policies and Procedures required by Section III.B;
- c. post a notice in accordance with the requirements of Section III.C;
- d. complete the training required for Covered Persons and Ordering Providers and maintain training records, in accordance with the requirements of Section III.D;
- e. screen Covered Persons in accordance with the requirements of Section III.F; require Covered Persons to disclose if they are excluded in accordance with the requirements of Section III.F; or maintain copies of print screens from search results to demonstrate the required screening has been performed in accordance with the requirements of Section III.F;
- f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;
- g. repay any Overpayments as required by Section III.H and Appendix B; or
- h. report a Reportable Event in accordance with Section III.I; and
- i. provide to OIG the certifications required by Section III.J relating to any third-party biller engaged by Center for Pain Management during the term of the IA.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Center for Pain Management fails to engage and use an IRO, as required by Section III.E, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Center for Pain Management 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 \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Center for Pain Management fails to submit any Quarterly Claims Review Report in accordance with the requirements of Section III.E and Appendix B or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

5. A Stipulated Penalty of \$1,000 for each day Center for Pain Management fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Center for Pain Management fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Center for Pain Management as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

7. A Stipulated Penalty of \$1,000 for each day Center for Pain Management fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Center for Pain Management fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

8. A Stipulated Penalty of \$1,000 for each day Center for Pain Management fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to Center for Pain Management stating the specific grounds for its determination that Center for Pain Management has failed to comply fully and adequately with the IA obligation(s) at issue and steps the Center for Pain Management shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date Center for Pain Management 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.

B. Timely Written Requests for Extensions

Center for Pain Management may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Center for Pain Management fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Center for Pain Management receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Center for Pain Management has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Center for Pain Management of: (a) Center for Pain Management's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, Center for Pain Management shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Center for Pain Management elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Center for Pain Management cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Center for Pain Management has materially breached this IA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this IA

1. *Definition of Material Breach.* A material breach of this IA means:

- a. a failure by Center for Pain Management to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;
- b. repeated violations or a flagrant violation of any of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by Center for Pain Management constitutes an independent basis for Center for Pain Management's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than three years per material breach. Upon a determination by OIG that Center for Pain Management has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify Center for Pain Management of: (a) Center for Pain Management's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Center for Pain Management shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Center for Pain Management has begun to take action to cure the material breach; (ii) Center for Pain Management is pursuing such action with due diligence; and (iii) Center for Pain Management has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Center for Pain Management fails to satisfy the requirements of Section X.D.3, OIG may exclude Center for Pain Management from participation in the Federal health care programs. OIG shall notify Center for Pain Management in writing of its determination to exclude Center for Pain Management. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Center for Pain Management’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Center for Pain Management may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Center for Pain Management of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, Center for Pain Management shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a

request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether Center for Pain Management was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Center for Pain Management shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders Center for Pain Management to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Center for Pain Management requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be whether Center for Pain Management was in material breach of this IA and, if so, whether:

- a. Center for Pain Management cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Center for Pain Management's receipt of the Notice of Material Breach: (i) Center for Pain Management had begun to take action to cure the material breach; (ii) Center for Pain Management pursued such action with due diligence; and (iii) Center for Pain Management provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Center for Pain Management, only after a DAB decision in favor of OIG. Center for Pain Management's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude

Center for Pain Management upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Center for Pain Management may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Center for Pain Management shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Center for Pain Management, Center for Pain Management shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

Center for Pain Management and OIG agree as follows:

A. This IA shall become final and binding on the date the final signature is obtained on the IA.

B. This IA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this IA.

C. OIG may agree to a suspension of Center for Pain Management's obligations under this IA based on a certification by Center for Pain Management that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Center for Pain Management is relieved of its IA obligations, Center for Pain Management shall be required to notify OIG in writing at least 30 days in advance if Center for Pain Management plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to and do not affect: (1) Center for Pain Management's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned Nosheen Hasan M.D. signatory represents and warrants that she is authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

**ON BEHALF OF NOSHEEN HASAN, M.D. AND CENTER FOR PAIN
MANAGEMENT, SC**

/Nosheen Hasan/
Nosheen Hasan, M.D.

4/29/20
DATE

/Nosheen Hasan/
Center for Pain Management, S.C.

4/29/20
DATE

/Stacy C. Gerber Ward/
Stacy C. Gerber Ward
von Briesen & Roper, s.c.

4/29/20
DATE

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

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

05/01/2020
DATE

/Jonathan L. Culpepper/
JONATHAN L. CULPEPPER
Associate Counsel
Office of Inspector General
U.S. Department of Health and Human Services

05/01/2020
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the IA.

A. IRO Engagement

1. Center for Pain Management shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The 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.4 of the IA or any additional information submitted by Center for Pain Management in response to a request by OIG, whichever is later, OIG will notify Center for Pain Management if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Center for Pain Management may continue to engage the IRO.

2. If Center for Pain Management engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Center for Pain Management shall submit the information identified in Section V.A.4 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, or any additional information submitted by Center for Pain Management at the request of OIG, whichever is later, OIG will notify Center for Pain Management if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Center for Pain Management may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Quarterly 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 Quarterly Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Quarterly 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 professional acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Quarterly Claims Review; and

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

C. IRO Responsibilities

The IRO shall:

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

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Quarterly 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 B to the IA.

D. Center for Pain Management Responsibilities

Center for Pain Management shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this IA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each Quarterly 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. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe the 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 Center for Pain Management in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Center for Pain Management shall have 30 days from the date of OIG's written notice to provide information regarding the 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 Center for Pain Management regarding its IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Center for Pain Management in writing that Center for Pain Management shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Center for Pain Management must engage a new IRO within 60 days of receipt of OIG's written notice. The final determination as to whether or not to require Center for Pain Management to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

QUARTERLY CLAIMS REVIEW

A. Quarterly Claims Review. The IRO shall conduct a review of Center for Pain Management's claims submitted to and reimbursed by the Medicare and Medicaid programs, to determine whether (a) the items and services furnished were medically necessary and appropriately documented, and whether the claims were correctly coded, billed, and reimbursed; and (b) whether any diagnostic testing ordered was medically reasonable and necessary, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed. The first three-month period shall begin 30 days following the Effective Date of this IA.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

- a. Overpayment: The amount of money Center for Pain Management has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A claim submitted by Center for Pain Management and for which Center for Pain Management has received reimbursement from the Medicare program or a state Medicaid program. Each Paid Claim shall include all line items for items or services furnished to a single patient on the same date of service.
- c. Population: The Population shall be defined as all Paid Claims during the three-month period covered by the Quarterly Claims Review.

2. *Quarterly Claims Sample*.

- a. Within 15 days following the end of each three-month period during the term of the IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of Center for Pain Management during the preceding three-month period (Quarterly

Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at <https://oig.hhs.gov/compliance/rat-stats/index.asp>.

- b. Center for Pain Management shall provide the IRO with a list of all Center for Pain Management's Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO.
- c. The randomly selected 30 Paid Claims shall be reviewed by the IRO based on the supporting documentation available at Center for Pain Management's office or under Center for Pain Management's control and applicable Medicare and state Medicaid program requirements to determine whether (a) the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed; and (b) whether any diagnostic testing ordered was medically reasonable and necessary.
- d. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Repayment of Identified Overpayments.* Center for Pain Management shall repay within 60 days any Overpayments identified by the IRO in the Quarterly Claims Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If Center for Pain Management determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Center for Pain Management shall repay that amount at the mean point estimate as calculated by the IRO. Center for Pain Management shall make available to OIG all documentation that reflects

the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Review Sample (and any related work papers) received from Center for Pain Management to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

- a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.
- b. Source of Data. A description of (1) the process used to identify claims in the Population, and (2) the specific documentation relied upon by the IRO when performing the Quarterly 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 contractor manual or bulletins (including issue and date), other policies, regulations, or directives).
- c. Review Protocol. A narrative description of how the Quarterly Claims Review was conducted and what was evaluated.
- d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each Quarterly Claims Sample and Center for Pain Management shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from Center for Pain Management after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Claims Review Report describing the process by

which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation.* A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings.*

a. Narrative Results.

- i. For the first Quarterly Claims Review Report only, a description of (a) Center for Pain Management's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing, and (b) a description of controls in place to ensure that all items and services billed to Medicare or a state Medicaid program by Center for Pain Management are medically necessary and appropriately documented. Subsequent Quarterly Claims Review Reports should describe any significant changes to items (a) and (b) or, if no significant changes were made, state that the systems and controls remain the same as described in the prior Quarterly Claims Review Report.
- ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Center for Pain Management differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Center for Pain Management.
- ii. Total number and percentage of instances in which the IRO

determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to Center for Pain Management.

- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Center for Pain Management.
 - iv. Total dollar amount of all Overpayments in the Quarterly Claims Review Sample.
 - v. Total dollar amount of Paid Claims included in the Quarterly Claims Review Sample.
 - vi. Error Rate in the Quarterly Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Quarterly Claims Review Sample by the total dollar amount associated with the Paid Claims in the Quarterly Claims Review Sample.
 - vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
 - viii. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Center for Pain Management's billing and coding system or to Center for Pain Management's 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 Quarterly Claims Review.

- d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation*. Any Paid Claim for which Center for Pain Management cannot produce documentation shall be considered an error and the total reimbursement received by Center for Pain Management for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples discussed in this Appendix, the Paid Claims selected in each first sample 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 sample).