

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JULIUS MINGRONI, D.O.**

I. PREAMBLE

Julius Mingroni, D.O. (“Mingroni”) hereby enters into this Integrity Agreement (“Agreement”) 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, program requirements, 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”) by Mingroni. This commitment to promote compliance applies to any entity that Mingroni owns or in which Mingroni has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Mingroni’s and any such entity’s Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Mingroni is entering into a Settlement Agreement with the OIG, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of compliance obligations assumed by Mingroni under this Agreement shall be three years from the effective date of this Agreement (“Effective Date”), unless otherwise specified. The Effective Date shall be the date on which the final signatory of this Agreement executes this Agreement. Each one-year period beginning with the one-year period following the Effective Date shall be referred to as “the Reporting Period.”

B. Sections VI, VII, VIII, IX, and X shall expire no later than 120 days from the OIG’s receipt of: (1) Mingroni’s final annual report; or (2) any additional materials submitted by Mingroni pursuant to the OIG’s request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. “Covered Persons” includes:
 - a. Mingroni and any co-owners, officers, directors, and employees of Mingroni;

b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Mingroni; and

c. all other individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports, or other requests for reimbursement for such items or services on behalf of Mingroni.

III. INTEGRITY OBLIGATIONS

Mingroni shall establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Mingroni shall designate a person to be responsible for compliance activities (“Compliance Contact”). The Compliance Contact shall: (1) develop and implement policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; and (2) shall respond to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, Mingroni shall notify the OIG, in writing, within 15 days after such a change.

B. Posting of Notice

Within the 30 days after the Effective Date, Mingroni shall post in a prominent place accessible to all patients and Covered Persons, a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report. An example of a notice is attached as Attachment 1.

C. Written Policies and Procedures

Within 90 days after the Effective Date, Mingroni shall develop, implement, and make available to all Covered Persons written policies that address the following:

1. Mingroni's commitment to operate his business in full compliance with all Federal health care program requirements, including his commitment to prepare and submit accurate claims consistent with such requirements;
2. Mingroni's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Mingroni's own Policies and Procedures, as implemented pursuant to this Section III.C (including the requirements of this Agreement);
3. The requirement that all of Mingroni's Covered Persons shall be expected to report to Mingroni or the Compliance Contact suspected violations of any Federal health care program requirements or Mingroni's own Policies and Procedures;
4. The commitment of Mingroni to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;
5. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and
6. The proper documentation of services and billing information and the retention of such information in a readily retrievable form.
7. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute or the Stark Law.
8. The requirements set forth in Section III.D.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has read, understood, and shall abide by Mingroni's Policies and Procedures. New Covered Persons shall receive and review the Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Mingroni shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date

of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, Mingroni and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 4 hours of training from an individual or entity, other than Mingroni or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for physician services provided by Mingroni and may be received from a variety of sources (i.e., CME classes, hospitals, associations, carriers).

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. The submission of accurate claims for services rendered and/or items provided to Federal health care program patients;
2. The written Policies and Procedures developed pursuant to Section III.C, above;
3. The legal sanctions for improper claims; and

4. Examples of proper and improper claims submission practices.
5. The legal sanctions for improper contracting or financial arrangement;
6. Examples of violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn;
7. A review of Mingroni's contracting Policies and Procedures related to Arrangements, as defined in Section III.E. below, as developed pursuant to Sections III.C. and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Mingroni's Policies and Procedures.

Each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date the training was received. Mingroni shall retain the certifications, along with all training course materials. The training course materials shall be provided in the Annual Report. The certifications shall be made available to the OIG, upon request.

E. Contractual Compliance with the Anti-Kickback Statute and the Stark Law

This Section shall apply to every arrangement or transaction that:

- (1) (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Mingroni and any actual or potential source of health care business or referrals to Mingroni or any actual or potential recipient of health care business or referrals from Mingroni. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- (2) is between Mingroni and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Mingroni for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

The arrangements and transactions described above, and the written versions thereof, are collectively referred to as "Arrangements." The party(ies) to an Arrangement other than

Mingroni shall be referred to herein as a “contractor.”

Within 90 days after the Effective Date of this Agreement, Mingroni shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or the Stark Law. Mingroni shall summarize all Arrangements in the form provided at Appendix A. Mingroni shall update the summary at Appendix A annually and shall submit the summary with each Annual Report.

Prior to entering into new Arrangements or renewing existing Arrangements, Mingroni shall ensure that all Arrangements are in compliance with the Anti-Kickback Statute and Stark Law, and the regulations, directives, and guidance related to these statutes, and comply with the following requirements:

1. The Arrangement shall be set forth in writing and signed by Mingroni and the contractor(s);
2. The Arrangement shall include a provision that all individuals who meet the definition of Covered Persons shall comply with Mingroni’s Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Mingroni shall provide each contractor with a copy of the Code of Conduct and Stark and Anti-Kickback Policies and Procedures;
3. Mingroni shall certify and shall require the contractor(s) to certify, at the time of signing the Arrangement and upon contract renewal, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and
4. Mingroni shall require the contractor(s) to certify, at the time of signing the Arrangement, that the contractor(s) shall comply with Mingroni’s compliance program and with the Anti-Kickback Statute and the Stark Law.

Mingroni shall retain and make available to the OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by Mingroni of his attorney-client,

attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Mingroni to avoid his obligations to comply with the provisions of this CIA.

F. Ineligible Persons

1. *Definition.* For purposes of this IA, an “Ineligible Person” shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements.* Mingroni shall ensure that all owners, officers, directors, employees, contractors, and agents of Mingroni are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, Mingroni shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists shall hereinafter be referred to as the “Exclusion Lists”). Nothing in this Section affects the responsibility of (or liability for) Mingroni to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days after the Effective Date, Mingroni shall review the list of the persons identified in Section III.G.2 against the Exclusion Lists. Thereafter, Mingroni shall review the list of such persons against the Exclusion Lists annually. In addition, Mingroni shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If Mingroni has actual notice that such person has become an Ineligible Person, Mingroni shall remove such person from responsibility for, or involvement with, Mingroni’s business operations related to the Federal health care programs and shall remove such person from any position for which the person’s compensation or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Mingroni has actual notice that a person identified in Section III.G.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, Mingroni shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this Agreement, an “Overpayment” shall mean the amount of money Mingroni has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, Mingroni identifies or learns of any Overpayment, Mingroni shall notify the payor (e.g., Medicare carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Mingroni shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Mingroni shall notify the payor of his efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor shall be handled in accordance with such policies and procedures.

2. *Reportable Event.*

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

- (i) a substantial Overpayment; or
- (ii) 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.

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

b. Reporting of Reportable Events. If Mingroni determines, by any means, that there is a Reportable Event, Mingroni shall notify the OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to the OIG shall include the following information:

(i) If the Reportable Event results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.G.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor’s name, address, and contact person to whom the Overpayment was sent; an

(B) the date of the check and identification number (or electronic transaction number) on which the Overpayment was repaid/refunded;

(ii) a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of Mingroni’s actions taken to correct the Reportable Event; and

(iv) any further steps Mingroni plans to take to address the Reportable Event and prevent it from recurring.

H. Notification of Government Investigations or Legal Proceedings

Within 30 days after discovery, Mingroni shall notify the OIG, in writing, of any ongoing investigation known to Mingroni or legal proceeding conducted or brought by a governmental entity or his agents involving an allegation that Mingroni 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. Mingroni shall also provide written notice to the OIG with a description of the findings and/or results of the proceedings, if any.

I. New Business Units, Locations or Relationships

In the event that after the Effective Date, Mingroni changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mingroni shall notify the OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the location of the new business unit or location, phone number, fax number, Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider or supplier number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

Prior to Mingroni entering into an employment or contractual relationship with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mingroni shall notify that party of this Agreement. This notification shall include a copy of the Agreement, the remaining reporting period of the Agreement, and a summary of Mingroni's obligations under the Agreement. In addition, Mingroni shall notify the OIG of such relationship as described in Section XI.D.

IV. REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Mingroni shall submit a written report to OIG summarizing the status of his implementation of the requirements of this Agreement. This Implementation Report shall include:

1. The name, address, and phone number of Mingroni's Compliance Contact;
2. A copy of the notice Mingroni posted in his office as described in Section III.B and a description of where and when the notice was posted;
3. A copy of the written policies and procedures required by Section III.C.;
4. A certification signed by Mingroni attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
5. A copy of all training materials used for the training required by Section III.D., a description of the training, including a summary of the topics covered, the length of the session(s), and a schedule of when the training session(s) were held;
6. A certification signed by Mingroni attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;
7. A summary of personnel actions (other than hiring) taken pursuant to Section III.F.;
9. A list of all Mingroni's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the name and address of the Medicare contractor to which Mingroni currently submits claims; and
10. A certification from Mingroni stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Mingroni shall submit to the OIG Annual Reports with respect to the status of and findings regarding Mingroni's compliance activities for each of the five Reporting Periods. The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the

OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. A certification by Mingroni that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;
2. A schedule, topic outline, and copies of the training materials for the training programs attended in accordance with Section III.D.;
3. A certification signed by Mingroni certifying that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D.;
4. A summary of Material Deficiencies (as defined in Section III.G.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
5. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;
6. A certification signed by Mingroni certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs;
7. A certification signed by Mingroni certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful; and
8. If revisions were made to the written Policies and Procedures developed pursuant to Section III.C., a copy of any policies and procedures that were revised.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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

Mingroni: Dr. Julius Mingroni
617 Blackhorse Pike
Blackwood, NJ 08012

Unless otherwise specified, all notifications and reports required by this Agreement shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VI. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Mingroni's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Mingroni's locations for the purpose of verifying and evaluating: (a) Mingroni's compliance with the terms of this Agreement; and (b) Mingroni's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Mingroni to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Mingroni's employees, contractors, or agents 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 the OIG. Mingroni shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Mingroni's employees may elect to be interviewed with or

without a representative of Mingroni present.

VII. DOCUMENT AND RECORD RETENTION

Mingroni shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six years (or longer if otherwise required by law).

VIII. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Mingroni prior to any release by OIG of information submitted by Mingroni pursuant to his obligations under this Agreement and identified upon submission by Mingroni as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Mingroni shall have the rights set forth at 45 C.F.R. § 5.65(d). Mingroni shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

Mingroni is expected to fully and timely comply with all of his Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Mingroni and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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) for each day Mingroni fails to:
 - a. have in place a Compliance Contact as required in Section III.A.;
 - b. post the notice required in Section III.B;
 - c. implement and make available the Policies and Procedures required in Section III.C;

- d. require that Covered Persons attend the training required by Section III.D. within the time frames required in that Section;
- e. submit the Implementation Report or the Annual Reports to OIG;
- f. meet the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Mingroni employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Mingroni's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Mingroni can demonstrate that Mingroni did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G.2.) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day Mingroni fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Mingroni fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Mingroni as part of his Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this Agreement.

5. A Stipulated Penalty of \$750 for each day Mingroni fails to comply fully and adequately with any obligation of this Agreement. In its Demand Letter pursuant to Section IX.C.1. to Mingroni, the OIG shall state the specific grounds for its determination that Mingroni has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Mingroni shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the receipt of the Demand Letter. A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

Mingroni 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

Agreement. Notwithstanding any other provision in this Section, if the 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 Mingroni fails to meet the revised deadline set by the OIG.

Notwithstanding any other provision in this Section, if the 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 Mingroni receives the 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 the 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 Mingroni has failed to comply with any of the obligations described in Section X.A. and after determining that Stipulated Penalties are appropriate, the OIG shall notify Mingroni of: (a) Mingroni's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Mingroni shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to the OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Mingroni elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Mingroni cures, to the 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 Agreement and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in Section VI.

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 the OIG's decision that Mingroni has materially breached this Agreement, which decision shall be made at the OIG's discretion and shall be governed by the provisions in Section X.D., below.

D. Exclusion for Material Breach of this Agreement

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

- a. a failure by Mingroni to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H.;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section IX.A.;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section IX.C.; or

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Mingroni constitutes an independent basis for Mingroni's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Mingroni has materially breached this Agreement and that exclusion shall be imposed, the OIG shall notify Mingroni of: (a) Mingroni's material breach; and (b) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Mingroni shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. Mingroni is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Mingroni has begun to take action to cure the material breach; (ii) Mingroni is pursuing such action with due diligence; and (iii) Mingroni has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Mingroni fails to satisfy the requirements of Section X.D.3, the OIG may exclude Mingroni from participation in the Federal health care programs. The OIG shall notify Mingroni in writing of its determination to exclude Mingroni (this letter shall be referred to hereinafter

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 the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Mingroni wishes to apply for reinstatement, Mingroni shall submit 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 the OIG’s delivery to Mingroni of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Mingroni 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 Agreement. Specifically, the 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 the 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.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Mingroni was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. Mingroni shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this Agreement and orders Mingroni to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Mingroni 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 the 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

- a. whether Mingroni was in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: (i) Mingroni had begun to take action to cure the material breach within that period; (ii) Mingroni has pursued and is pursuing such action with due diligence; and (iii) Mingroni provided to the OIG within that period a reasonable timetable for curing the material breach and Mingroni has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Mingroni, only after a DAB decision in favor of the OIG. Mingroni's election of his contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Mingroni upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Mingroni may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Mingroni shall waive his 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 Mingroni, Mingroni 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 Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

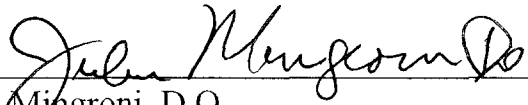
X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Mingroni and the OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns, and transferees of Mingroni;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;

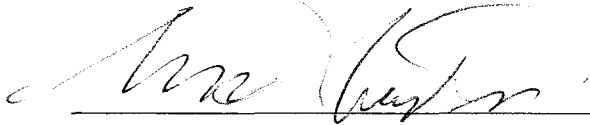
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. If Mingroni enters into an employment or contractual relationship with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Mingroni shall notify the OIG within 30 days after the date of the establishment of such relationship. Upon receipt of Mingroni's notification, the OIG may request information regarding the party's compliance program. The OIG may agree to modify the Agreement based on its evaluation of Mingroni's new business relationship, his role in such relationship, and the party's compliance program.
- E. The OIG may agree to a suspension of Mingroni's obligations under this Agreement in the event of Mingroni's cessation of participation in Federal health care programs. If Mingroni withdraws from participation in Federal health care programs and is relieved from his Agreement's obligations by the OIG, Mingroni shall notify the OIG 30 days in advance of Mingroni's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, the OIG shall evaluate whether the Agreement shall be reactivated or modified.
- F. The undersigned Mingroni signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

FOR DR. JULIUS MINGRONI



Julius Mingroni, D.O.
617 Blackhorse Pike
Blackwood, NJ 08012

8/27/03
Date




Nick Nastasi, Esq.
241 South Seventh Street
Philadelphia, PA 19106

8/27/03
Date

Counsel for Dr. Mingroni

FOR THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

8/28/03
Date

ATTACHMENT 1

NOTICE

Physician Organization ABC is committed to complying with all Federal health care program requirements in the operation of its business.

Anyone who has information or concerns about a possible violation of *ABC's* policies and procedures or any Federal health care program requirements should contact the Compliance officer at *(123) 456-7890* or via email at *physicianorg@abc.net*. Reporting may also be made anonymously by sending correspondence to:

John Doe
Physician Organization ABC
000 Circle Dr.
New Town, ST 10000
Fax: (123) 456-7788

APPENDIX B

OVERPAYMENT REFUND FORM

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
Contractor Deposit Control # _____
Date of Deposit: _____
Contractor Contact Name: _____
Phone #: _____
Contractor Address: _____
Contractor Fax #: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
ADDRESS _____
PROVIDER/PHYSICIAN/SUPPLIER # _____
CHECK NUMBER# _____
CONTACT PERSON: _____
PHONE# _____
AMOUNT OF CHECK \$ _____
CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____
HIC # _____
Medicare Claim Number _____
Claim Amount Refunded \$ _____
Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to

Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____

(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have an Integrity Agreement with OIG? Yes No

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Ins.	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp. (Including Black Lung)	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		