BEFORE THE NEVADA STATE BOARD OF OSTEOPATHIC MEDICINE

IN THE MATTER OF:
MICHICLLE HYLA, D.O.
License No. 1172,
Respondent.

Case No. AD1407001
SETTLEMENT AGREEMENT AND
ORDER

The Nevada State Board of Osteopathic Medicine (the Board), by and through its investigating board member Nicole Cavenagh, PhD., hereby enters into this settlement agreement with Michelle Hyla, D.O. (License No. 1172). Pursuant to chapter 233B and chapter 633 of the Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC), it is hereby stipulated and agreed, by and between the parties in the above-entitled matter, that this matter shall be fully and finally settled and resolved upon terms and conditions set out herein.

PERTINENT FACTS

1. On July 1, 2004, Dr. Hyla became licensed by the Board to practice as an osteopathic physician in Nevada (License No. 1172). The Board’s records show that Dr. Hyla is board certified in Pediatrics. Dr. Hyla’s practice address of record with the Board is De Novo Clinic, 9330 W. Sahara Avenue, Las Vegas, Nevada 89117.

2. On July 11, 2014, the Board’s Executive Director filed a complaint against Dr. Hyla based upon information provided to her. The information received indicated that Dr. Hyla was the “medical director” for a weight loss practice called De Novo Clinic, 9330 W. Sahara Avenue in Las Vegas, Nevada. The information also indicated that an employee of De Novo was ordering, receiving, and administering dangerous drugs without Dr. Hyla being present and sometimes via prescriptions signed in advance by Dr. Hyla. Thereafter, the Board’s staff commenced an investigation.

3. The Board’s investigation determined that Dr. Hyla became the “medical director” at a weight loss practice that was operating under the name De Novo Clinic, 9330 W. Sahara Avenue in Las Vegas, Nevada (hereinafter “De Novo”) in July 2013. De Novo is owned by Ms. Carol Chaney who is licensed in Nevada as a Registered Nurse. De Novo represented and advertised itself to the public as a medical clinic specializing in weight loss treatments. At all times pertinent to this matter, Dr. Hyla did have a DEA
registration and a Nevada controlled substances registration (CS) registered to the De Novo location and
also registered to Positively Kids Family Health Care at 701K North Pecos Road in Las Vegas, Nevada.
Dr. Hyla did not have a dispensing registration at the De Novo location.

3. On July 14, 2014, investigators from the Nevada Board of Pharmacy visited the De Novo
premises. Because no person with lawful authority to possess the dangerous drugs was registered or
present at De Novo on July 14, 2014 and because some of the drugs discovered at De Novo were
otherwise in violation of Nevada pharmacy law, the investigators for the Nevada State Board of Pharmacy
impounded the following dangerous drugs from De Novo:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha Lipoic Acid 15 mg./ml. #30 ml.</td>
<td>1</td>
</tr>
<tr>
<td>Methylcobalamin 1 mg./ml. #30 ml.</td>
<td>2*</td>
</tr>
<tr>
<td>Methionine/Inositol/Choline #30 ml.</td>
<td>1*</td>
</tr>
<tr>
<td>Hydroxocobalamin 1 mg./ml. #30 ml.</td>
<td>1*</td>
</tr>
<tr>
<td>Biotin 10 mg./ml. #30 ml.</td>
<td>2+</td>
</tr>
<tr>
<td>Vitamin D3 50,000 IU #5 ml.</td>
<td>1*</td>
</tr>
<tr>
<td>My-O-Den Injectable #30 ml.</td>
<td>35</td>
</tr>
<tr>
<td>RX #1902997 (Prescriber Dr. Hyla)</td>
<td>1</td>
</tr>
<tr>
<td>RX #1075196 (Prescriber Dr. Hyla)</td>
<td>1</td>
</tr>
<tr>
<td>RX #1069904 (Prescriber Dr. Hyla)</td>
<td>1</td>
</tr>
</tbody>
</table>

* - found in an opened state with no date of breach of the seal noted
+ - expired because older than one year

5. In the course of the investigation, Dr. Hyla was interviewed and also provided several written
statements to the Board. Dr. Hyla explained that the patient care model at De Novo involved two types
of weight loss programs, one a “natural” program that did not involve any prescription drugs and the
other that involved injections of vitamin B12 and Human Chorionic Gonadotropin (HCG). In Nevada,
vitamin B12 injections are dangerous drugs and must be prescribed by a physician, and HCG is a
controlled substance in schedule III that also must be prescribed by a physician. Dr. Hyla explained that
most of De Novo’s patients wanted the prescription drugs, and for such patients, she would usually come into the practice to examine the patients before prescribing the drugs. Dr. Hyla or another member of De Novo’s staff would educate the patient regarding self-injection because the practice’s model was that the practice would not administer injections and opted, instead, to send prescriptions to one of two pharmacies which would then fill the prescriptions and send them to the practice where the practice would then dispense the prescription drugs to the patients. Though Dr. Hyla believed that no HCG injections were administered on the De Novo premises, Dr. Hyla knew that B12 injections were routinely administered to patients by staff at De Novo at times when Dr. Hyla was not on the De Novo premises. Additionally, it was the regular practice of De Novo to dispense the prescription injectable to patients at times when Dr. Hyla was not on the De Novo premises.

6. Dr. Hyla also acknowledged that she allowed several members of the De Novo staff to order dangerous drugs without her involvement or oversight. Upon their receipt, the prescription drugs would be stored in a room that contained a locking container, but Dr. Hyla acknowledged that the prescription drugs were always available to De Novo’s staff regardless of Dr. Hyla presence or absence.

ACKNOWLEDGMENTS AND APPLICABLE LAW

7. Dr. Hyla admits that the facts contained in the preceding six paragraphs are true and correct, and Dr. Hyla understands and acknowledges that the conduct set out in the preceding six paragraphs constitute violations of Nevada law and that she agrees that she is subject to disciplinary action by the Board as a result of that conduct. In particular, Dr. Hyla agrees that the facts contained in the preceding six paragraphs constitute violations of Nevada Revised Statutes (NRS) 633.511(1) as unprofessional conduct as further defined in NRS 633.131(1)(g) and (k) and NRS 639.23505 and Nevada Administrative Code (NAC) 633.350(1)(k) and NAC 639.742. Because of these admissions, the Board will not file an Accusation in this matter and the parties agree, instead, that the Board should rule upon this Settlement Agreement and Order as containing all necessary elements of due process to authorize the Board to take such action. If the Board approves this Settlement Agreement and Order, it shall be deemed and considered disciplinary action by the Board against Dr. Hyla.

8. Dr. Hyla and Dr. Cavenagh, the Investigating Board Member in this matter, agree that it is in the best interests of Dr. Hyla and the Board to resolve this matter without a full hearing on the merits.
9. Dr. Hyla is aware of, understands, and has been advised of the effect of this Settlement Agreement, which she has carefully read and fully acknowledged. Dr. Hyla acknowledges that she reviewed this Settlement Agreement and that she was provided the opportunity to review this Settlement Agreement with legal counsel of her own choice, which Dr. Hyla declined to do.

10. Dr. Hyla has freely and voluntarily entered into the Settlement Agreement, and she is aware of her rights to contest the charges pending against her. These rights include representation by an attorney at her own expense, the right to a public hearing on any charges or allegations formally filed, the right to confront and cross-examine witnesses called to testify against her, the right to present evidence on her own behalf, the right to testify on her own behalf, the right to obtain any other type of formal judicial review of this matter, and any other rights which may be accorded to her pursuant the provisions of Chapters 233B, 622, 622A, and 633 of the NRS and the NAC. Dr. Hyla is voluntarily waiving all these rights in exchange for the Board’s acceptance of this Settlement Agreement.

11. Should the Settlement Agreement be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Settlement Agreement or other documents or matters pertaining to the consideration of this Settlement Agreement shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, adjudication, or resolution of these proceedings and that no Board member shall be disqualified or challenged for bias.

12. Dr. Hyla for herself, her executors, administrators, successors, and assigns hereby releases and forever discharges and holds harmless the State of Nevada, the Nevada Board of Osteopathic Medicine and each of their members, agents, investigators and employees in their individual and representative capacities, from any and all manner of actions, causes of action, suit, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Licensee ever had, now has, may have or claim to have against any or all of the persons or entities named in this paragraph arising out of or by reason of this investigation, this disciplinary action, this settlement agreement or its administration.

13. In consideration for the execution of the settlement agreement, Dr. Hyla hereby releases and forever discharges the State of Nevada, the Board of Osteopathic Medicine, and the Nevada Attorney General’s Office (as counsel for the Board), and each of their representatives, investigators, and employees, in their individual and representative capacity from any and all manner of actions, causes of
actions, suits, debts, judgments, executions, claims and demands whatsoever, known or unknown, in law
and in equity, that she may have had, now has, or claim to have against any and all of the persons and
entities named in this paragraph arising out of or by reason of the investigation of the allegations raised
herein and other matters relating thereto.

14. Dr. Hyla acknowledges that the Settlement Agreement shall only become effective after both
the Board and she have duly executed it.

15. Dr. Hyla enters into this settlement agreement voluntarily after being fully advised of her
rights and as to the consequences of this settlement agreement. This settlement agreement embodies the
entire agreement reached between the Board and Dr. Hyla. It may not be altered, amended, or modified
without the express consent of the parties.

16. Both parties acknowledge that the Board has jurisdiction to consider and ratify this
settlement agreement and order because Dr. Hyla is an osteopathic physician licensed by the Board. Dr.
Hyla expressly, knowingly, and intentionally waives the 21-day notice requirement contained in the
Nevada Open Meeting Law and acknowledges that this settlement agreement and order may be presented
to the Board for its consideration and potential ratification at the Board’s meeting on October 14, 2014.

AGREED DISCIPLINARY ACTION

THE PARTIES DO HEREBY AGREE as a result of the admissions and acknowledgements
contained in paragraphs 1 through 16 above that the following discipline is fair and appropriate and
should be imposed by the Board by way of resolution of this matter:

1. Dr. Hyla shall pay the Board’s fees and costs in the investigation and prosecution of this
matter totaling $1,500.00, payable by cashier’s or certified check or money order made payable to:
“Nevada State Board of Osteopathic Medicine.” Payment shall be due within 90 days of the effective date
of this Settlement Agreement and Order, but if Dr. Hyla cannot make payment in full by that time, she
may make payment arrangements with as are acceptable to the Board’s Executive Director.

2. Dr. Hyla shall pay a fine of $1,500.00 in this matter, payable by cashier’s or certified check or
money order made payable to: “Nevada State Board of Osteopathic Medicine.” Payment shall be due
within 90 days of the effective date of this Settlement Agreement and Order, but if Dr. Hyla cannot make
payment in full by that time, she may make payment arrangements with as are acceptable to the Board’s
Executive Director.

3. Dr. Hyla shall not administer, prescribe, or dispense any controlled substances or dangerous
drugs from De Novo or any other practice site from which she practices unless and until she satisfies the
following conditions:

(a) Dr. Hyla obtains a DEA registration and Nevada CS registration at the site. Dr. Hyla shall also
register the site as a practice site with the Board. If Dr. Hyla desires to dispense controlled substances or
dangerous drugs from the site, she must also obtain a Nevada dispensing practitioner’s registration. Dr.
Hyla shall provide written evidence of her registrations to the Board office.

(b) Dr. Hyla secures the only key to the room in which the controlled substances and dangerous
drugs are stored such that only Dr. Hyla unlocks the door every day that controlled substances and
dangerous drugs are to be administered and that Dr. Hyla locks the door whenever controlled substances
and dangerous drugs are not being administered to patients.

(c) Dr. Hyla must personally see and assess each patient at the site to determine that the patient
has a valid medical condition or diagnosis for which a particular controlled substance or dangerous drug
is appropriate. Dr. Hyla must make a medical record regarding each patient she sees and assesses at the
site, which record must include the basic physical examination information, Dr. Hyla’s assessment,
diagnoses, and controlled substances or dangerous drugs administered. The medical records made
pursuant to this subparagraph must be maintained at the site. Dr. Hyla may employ a physician assistant
or advanced practitioner of nursing under her supervision to see and assess the patients of the site and to
make and maintain the records in the same manner as is required of Dr. Hyla under this paragraph.

(d) Dr. Hyla shall provide to the Board office her policy and procedures that will be used at De
Novo (or any other practice site) for the seeing, assessment, diagnosis, administering, prescribing, and
dispensing of controlled substances and dangerous drugs to patients at the site. Dr. Hyla may not
commence administering, prescribing, or dispensing controlled substances and dangerous drugs from any
site until her policy and procedures have been reviewed and approved by the Investigating Board
Member.
4. For any controlled substance or dangerous drug packaged by and sold by the manufacturer as single-patient use only (such as Botox), Dr. Hyla may only administer controlled substances or dangerous drugs from any such packaging to a single patient, and if the entire quantity is not used on that patient for that visit, the remainder shall be wasted and not used on another patient.

5. Dr. Hyla shall meet with the Board or its representatives upon request and shall cooperate with such representatives in their supervision, monitoring, investigation, or auditing to assure compliance with the terms and conditions of this order. Dr. Hyla shall pay any and all reasonable and necessary costs incurred by the Board resultant from this paragraph.

6. In the event Dr. Hyla fails to materially comply with any term of this Settlement Agreement, Dr. Hyla agrees her license in the State of Nevada shall be automatically suspended without any action of the Board other than the issuance of an Order of Suspension by the Executive Director. Upon complying with the term, Dr. Hyla's license in the State of Nevada will be automatically reinstated, assuming all other provisions of the Settlement Agreement are in compliance. Additionally, Dr. Hyla's failure to comply with any term or condition of this Settlement Agreement may result in further discipline by the Board, up to and potentially including revocation of her license. Board Staff may take any and all actions it deems necessary to collect any sums ordered that remain unpaid. If Board Staff is required to pursue judicial action to effect such collections, it shall be entitled to recover its attorney's fees and costs incurred in pursuing such judicial action.

Signed this 25th day of September, 2014.

Respondent Michelle Hyla

By Michelle Hyla, D.O., Respondent

Nevada State Board of Osteopathic Medicine

By Nicole Cavenagh, PhD
Investigating Board Member
ORDER

WHEREAS, on October 14, 2014 the Nevada State Board of Osteopathic Medicine approved and adopted the terms and conditions set forth in the Agreed Settlement and Order with Michelle Hyla, D.O. IT IS SO ORDERED.

SIGNED AND EFFECTIVE this 14 day of October, 2014.

NEVADA STATE BOARD OF OSTEOPATHIC MEDICINE

[Signature]
Ronald Hedger, D.O.
Chairman
BEFORE THE NEVADA STATE BOARD OF OSTEOPATHIC MEDICINE

IN THE MATTER OF THE COMPLAINT

AGAINST

MICHELLE HYLÀ, D.O.

License No. 1172

RESPONDENT.

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of October, 2014, I served a copy of the ABOVE Notice with attachment upon the parties to this matter, via U.S. Postal Service, postage thereon prepaid, at their last known address on file with this Board.

Michelle Hyla, D.O.

[Signature]

An employee of the Nevada State Board of Osteopathic Medicine