### **NON-PROSECUTION AGREEMENT**

The United States Attorney's Offices for the Central District of California and Southern District of California (collectively "USAO") hereby enter into the following Non-Prosecution Agreement (the "Agreement") with National Spine and Pain Centers, LLC ("NSPC," or the "Company"), a Delaware limited liability company, pursuant to authority granted by the Company's Board of Directors as reflected in <a href="Exhibit D">Exhibit D</a>, to resolve the federal criminal investigation under, among other statutes, Title 18, United States Code, Section 371 and Title 42, United States Code, Section 1320a-7b. This Agreement is binding only on the Company and the USAO; it specifically does not bind any other component of the Department of Justice; other federal agencies, or any state, local or foreign law enforcement or regulatory agencies; or any other authorities.

## I. <u>Introduction and Relevant Considerations</u>

- 1. The USAO enters into this Agreement with NSPC based on the individual facts and circumstances presented by this case and the Company, including the following factors:
  - a. The Company's demonstrated commitment to compliance, including the following:
    - i. Prior to the commencement of the investigation and following an acquisition of NSPC by a new ownership group, the Company has focused on implementing a compliance program for its affiliated practices specifically designed to ensure that its practice operations conform with the federal Anti-Kickback Statute ("AKS"), including through the adoption of policy development, trainings, auditing and detection protocols, and investigatory mechanisms intended to combat fraud, waste, and abuse;
    - NSPC's compliance program uses in-house staff and outside compliance consultants to audit, monitor, counsel, and respond to alleged instances of non-compliance. NSPC has a Compliance Risk Assessment Policy that provides for annual compliance risk assessments focused on the developing regulatory environment in pain management and emerging risk areas under the AKS;
    - iii. NSPC has implemented 37 health care compliance policies addressing risks inherent to pain management as well as risk areas identified in the course of annual risk assessments, which are readily accessible to all practice personnel, who are trained at least annually on the Company's adopted policy requirements and standards; and
    - iv. All practice personnel receive regular training on "incident-to" and related Medicare billing requirements, including annual training, "refresher" training as needed, and additional training when billing and coding requirements change. NSPC also has a billing and coding auditor who audits billing and provides monthly training to practice personnel.

- b. The Company's cooperation with the USAO's investigation, which has assisted the government's efforts and has included:
  - i. The Company's early engagement with the USAO, including making factual presentations to the USAO;
  - ii. Producing documents and data to the USAO relating to Proove Biosciences, Inc. ("Proove"), a commercial genetic testing laboratory located in Irvine, California, as well as documents relating to the Company and certain of its affiliated physicians' involvement with Proove; and
  - iii. Making certain Company employees available for interviews or meetings with the USAO.
- c. The Company's acceptance of responsibility for its conduct, as described in the "Summary of Conduct" section of the Statement of Facts;
- d. The Company's voluntary undertaking of remedial measures, including the voluntarily termination of the relationship with Proove on March 3, 2017, prior to the Company's knowledge of the USAO's investigation and prior to the acquisition of NSPC by a new ownership group;
- e. The USAO's determination, based upon the Company's existing compliance program and remediation, that an independent compliance monitor is unnecessary; and
- f. The Company's agreement (in accordance with Paragraphs 4 through 7 of this Agreement) to continue to cooperate with the USAO, FBI, and HHS-OIG, during the pendency of the prosecution the USAO has instituted in this matter.

### II. The Term of the Agreement

2. This Agreement shall be deemed effective as of the last date of execution by a party to this Agreement (the "Initial Effective Date") and shall continue in effect for a period of 24 months (2 years) from the Initial Effective Date (the "Term"). Notwithstanding the foregoing, the Company's cooperation obligations as described in Paragraphs 4 through 7 of this Agreement shall continue until the conclusion of the prosecution (through the entry of final judgment) of the pending indictment of certain of the Company's affiliated physicians and any other defendants charged in the same or any related case. The Company further agrees that in the event of a breach by the Company, if the Company has failed to remedy such breach after receiving notice from the USAO, then an extension or extensions of the Term of up to 6 months, per breach, may be imposed by the USAO, without prejudice to the USAO's right to proceed as provided in Paragraphs 12 through 14 below. Any extension of the Term extends all terms of this Agreement for an equivalent period.

## III. The Company's Acceptance of Responsibility

3. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents within the scope of their employment, as set forth in the Statement of Facts. The Company agrees that the factual statements contained within the Statement of Facts are true and accurate.

## IV. Cooperation

- 4. At the request or direction of the USAO, the Company shall cooperate fully with the pending prosecution, and any related civil or administrative enforcement proceedings undertaken by the USAO or other federal law enforcement or regulatory authority or agency relating to this matter. All such cooperation described in this Paragraph shall include, but not be limited to:
  - Timely providing upon oral or written request, and in accordance with federal law, all non-privileged information, documents, records, and other tangible evidence that can be obtained through reasonable efforts, including from the Company and its affiliates;
  - b. Identifying, upon oral or written request, witnesses who, to the knowledge of the Company, may have material information regarding the matters under indictment; and
  - c. Upon oral or written request, using its best efforts to make available for interview or testimony, in a timely fashion, any current officer, executive, director, employee, agent, or consultant of the Company, including by making such persons available in the Central or Southern District of California, at the Company's expense, regardless of their location of residence.
- 5. The Company shall provide complete, truthful, and accurate information to the USAO/FBI/HHS-OIG. The Company's obligation to cooperate pursuant to the preceding paragraph will no longer apply if a prosecution by the USAO is commenced against the Company as a result of a breach of this Agreement.
- 6. With respect to any information, testimony, documents, records, or other tangible evidence provided pursuant to this Agreement, the Company consents to any and all disclosures, subject to applicable law and regulations, to other governmental and regulatory authorities, including United States authorities and those of a foreign government, of such materials as the USAO, in its sole discretion, shall deem appropriate.
- 7. Nothing in this Agreement is intended to request or require the Company to waive its attorney-client privilege or work product protections, and no such waiver shall be deemed effected by any provision herein.

### V. Financial Payment

- 8. The Company agrees to pay to the United States five million, one hundred thousand dollars (\$5,100,000) (the "Financial Payment") within fourteen (14) calendar days of the Initial Effective Date of the Agreement. The Financial Payment shall be paid by wire transfer payable to "CMS" and will identify "NSPC NPA" as the payer. The payment can be provided to CMS pursuant to the instructions provided in Exhibit E, with email confirmation of the same provided to the USAO.
- 9. The Company and the USAO agree that the Financial Payment is appropriate given the facts and circumstances of this case, including the Company's compliance program efforts, its efforts at cooperation, its disclosure of relevant facts, including information relating to the individuals involved in the investigated conduct, and the Company's extensive remediation in this matter. The Financial Payment is final and shall not be refunded. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of this Financial Payment. From and after the date hereof, the Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the Financial Payment that it pays pursuant to this Agreement.

#### VI. Non-Prosecution

- 10. The USAO agrees that if the Company fully complies with all of its obligations under this Agreement, the USAO will not criminally prosecute the Company, or any of its parents, subsidiaries or direct and indirect affiliates, including but not limited to Physical Medicine Associates, Ltd. ("PMA"), during the Term of this Agreement or thereafter for any crime related to the conduct described in the Statement of Facts. The USAO and the Company intend for this Agreement to resolve the USAO's criminal investigation of the Company and PMA relating to the conduct described in the Statement of Facts.
- 11. Except as expressly provided in Paragraph 10 above, this Agreement does not preclude or limit the USAO, any other United States Attorney's Office, or the United States Department of Justice from investigating or prosecuting the Company, or for prosecuting any other individual or entity, including any current or former officer, employee, or agent of the Company.

### VII. Breach of Agreement

12. If, during the Term, (a) the Company provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (b) the Company knowingly fails to cooperate as set forth in Paragraphs 4 through 7 of this Agreement; or (c) the Company otherwise knowingly and materially fails to perform or fulfill any of its obligations under the Agreement – and has failed to remedy such breach after receiving notice from the USAO as set forth in Paragraph 13 – the USAO will deem the Company in breach of the Agreement and the Company shall thereafter be subject to prosecution for any federal criminal violation, including, but not limited to, charges arising from the conduct described

- in the Statement of Facts. The determination whether the Company has breached the Agreement shall be in the USAO's sole discretion.
- 13. In the event that the USAO determines that the Company has breached this Agreement, the USAO shall provide the Company with written notice of such determination prior to instituting any prosecution resulting from such breach. Within 30 days of receipt of such notice, the Company shall have the opportunity to address such a breach by providing a response to the USAO to demonstrate that no breach has occurred, to demonstrate that the breach was not a knowing breach, and/or to explain the actions taken to address and remediate the breach. The USAO shall thereafter provide written notice to the Company of its final determination regarding whether to declare the Agreement breached. The Company shall thereafter have 30 days to appeal to a higher authority within the Department of Justice in order to obtain a written finding that, based on a preponderance of the evidence, the Company has not breached the Agreement. In the absence of such a written finding, the USAO's determination of breach shall become final after 30 days following the USAO's written notification.
- 14. In the event that the USAO determines to institute a criminal prosecution against the Company after a breach of this Agreement, then:
  - a. All statements made by or on behalf of the Company to the USAO, including the attached Statement of Facts, shall be admissible in evidence in any and all criminal proceedings brought by the USAO against the Company, and the Company shall stipulate to the admissibility into evidence of the Statement of Facts as an admission by the Company, and shall be precluded from offering any evidence or argument that contradicts the Statement of Facts or that suggests those facts are untrue or misleading;
  - b. The Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements made by or on behalf of the Company prior or subsequent to this Agreement should be suppressed or are otherwise inadmissible;
  - c. The USAO shall immediately be free to use the waiver of indictment provided by the Company in <a href="Exhibit B">Exhibit B</a> attached hereto and to prosecute the Company by way of information for any federal offense arising out of the Statement of Facts. The Company remains bound by all other waivers expressly made as part of this Agreement; and
  - d. The Company will not assert that the bringing of charges based upon the conduct outlined in the attached Statement of Facts is barred by the statute of limitations with respect to the period starting with the date of this Agreement.

#### VIII. Sale, Merger, or Other Change in Corporate Form of the Company

15. This Agreement shall be binding upon the Company, its successors and assigns. Except as may otherwise be agreed by the parties in connection with a particular transaction, the

Company agrees that in the event that, during the Term or during the pendency of its cooperation obligations described in Paragraphs 4 through 7 the Company sells, assigns, or otherwise directly transfers all or substantially all of its business to another person, whether such sale is structured as an asset sale by the Company, merger of the Company into another person, transfer by the Company, or change in corporate form of the Company, such business shall continue to be subject to the terms and conditions of this Agreement.

## IX. Certification

16. Thirty (30) days prior to the end of the Term, the Company will provide to the USAO a certification signed by a Company representative and counsel stating that it has met the conditions set forth in Sections II - IV of this Agreement. Such certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001 (false statement to federal agency) and 18 U.S.C. § 1505 (obstruction of federal proceeding), and it will be deemed to have been made in the Central District of California.

### X. Notice

17. Any notice to the USAO under this Agreement shall be provided (1) via email to joseph.green@usdoj.gov; and (2) personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Joseph S. Green U.S. Attorney's Office Southern District of California 880 Front Street San Diego, CA 92101

Any notice to the Company under this Agreement shall be provided (1) via email to Neil Kunkel, NKunkel@treatingpain.com and (2) personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Neil Kunkel, Chief Legal Officer National Spine and Pain Centers, LLC 11921 Rockville Pike, Suite 505 Rockville, MD 20852

-and-

Patrick Collins King & Spalding LLP 110 N Wacker Drive, Suite 3800 Chicago, IL 60606

18. Notice shall be effective upon actual receipt by the USAO or the Company.

## XI. Jurisdiction and No Other Agreements

19. This Agreement is covered by the laws of the United States. The USAO and the Company agree that exclusive jurisdiction and venue for any dispute arising under this Agreement is in the United States District Court for the Central District of California.

This Agreement, with its attached Exhibits A through E, sets forth all the terms of the agreement between the Company and the USAO. No modifications or additions to this Agreement, or to its attached Exhibits A through E, shall be valid unless they are in writing and signed by the USAO, the Company's attorneys, and a duly authorized agent of the Company.

Exhibit A – Statement of Facts

Counsel for National Spine and Pain Centers, LLC

Exhibit B – Waiver of Indictment

Exhibit C – Company Officer's Certificate

Exhibit D – Certificate of Counsel

Exhibit E – Medicare Restitution Payment Submission Instructions

#### AGREED:

AGREED:	
Tracy L. Wilkinson	
Acting United States Attorney	
Sant gr	8/3/31
Scott M. Garringer	DATE
Assistant United States Attorney	
Chief, Criminal Division	
Central District of California	
David D. Leshner	
Deputy United States Attorney	
April I Sur_	8/4/2021
Jøseph S. Green	DATE
Assistant Inited States Attorney	
N ell Kull	8/3/2021
National Spine and Pain Centers, LLC	DATE
by: Neil Kunkel, Chief Legal Officer	
Colle	8/3/2021
Patrick Collins	DATE
King & Spalding LLP	

#### **EXHIBIT A**

### STATEMENT OF FACTS

1. The following Statement of Facts is incorporated by reference as part of the Non-Prosecution Agreement (the "Agreement") between the United States Attorney's Office for the Central District of California, the United States Attorney's Office for the Southern District of California, and National Spine and Pain Centers, LLC ("NSPC" or the "Company"). NSPC hereby admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, agents, and affiliates, as set forth below:

#### **Relevant Parties**

- 2. NSPC was, at all times relevant to the conduct described herein, a Management Services Organization providing contractually agreed-upon administrative services to Physical Medicine Associates, Ltd. ("PMA").
- 3. PMA was, at all times relevant to the conduct described herein, a Virginia-based professional corporation providing interventional pain management services.
- 4. Proove Biosciences, Inc. ("Proove") was, at all times relevant to the conduct described herein, a company headquartered in Irvine, California. Proove operated a medical laboratory, Proove Medical Laboratories, Inc., also in Irvine, California.

## **Summary of Conduct**

- 5. In September 2013, representatives of PMA and NSPC began to discuss a potential collaboration with Proove to participate in a clinical research study relating to genetics testing that Proove was offering for Medicare patients as well as certain commercially-insured patients.
- 6. Proove marketed its study as a means of evaluating the clinical utility of Proove's proprietary genetic testing, which could provide participating physicians with information to improve the selection, dosing, and evaluation of pain medication based on patient genetics. Proove also marketed its study as a means for NSPC and PMA to earn revenue through payments as investigators. To participate in Proove's clinical research program, physicians necessarily had to order Proove's genetic tests for patients.
- 7. PMA entered into a contractual arrangement with Proove, which was styled as a Professional Services Agreement (the "PSA"), on June 12, 2014. The internal vetting of the PSA and approval of the Proove program would not have met the compliance standards of NSPC's current ownership. In some NSPC and PMA internal communications, certain physicians referred to the clinical research compensation payments being offered by Proove and a competing company as being payments "per test" or "per patient."
- 8. Under the PSA, PMA was to be compensated at an hourly rate of two hundred (\$200) dollars for each hour of research service provided and documented by the participating physicians. Compensation was purportedly conditioned upon the submission of time sheets

detailing the specific services rendered, including the date and amount of time physicians spent performing these services on behalf of Proove.

- 9. To record the time participating physicians spent performing clinical research services, Proove provided a form known as an Official Documentation and Daily Time Record (also known as an Official Time Record or "OTR"). The OTR required entries documenting the date of service, patient, functions performed, and time spent (in minutes). The OTR included a physician attestation providing that the time spent was "actually worked" by the physician for services provided under the PSA.
- 10. Under the arrangement, Proove placed employees known as Research Assistants ("RAs," later known as Patient Engagement Representatives or "PERs") on-site at participating physician practices. RAs were trained to, among other things, discuss Proove's genetic tests with patients, collect DNA samples, and to complete the consent forms, testing agreements, clinical research forms, and OTRs, many of the tasks associated with Proove's clinical research study.
- 11. All of the participating physicians completed OTRs. Some of those OTRs overstated the time participating physicians spent on the study described in the PSA. Additionally, in some cases, the OTRs indicated that physicians had performed certain tasks that were completed by the Proove employee. This resulted in physicians being paid for tasks that they did not complete and for time that they did not actually spend working on Proove's study. Proove, in turn, billed Medicare for the tests ordered by participating physicians. PMA was paid by Proove based on the OTRs, including timesheets that were inaccurate, in violation of 42 U.S.C. § 1320a-7b(b)(1)(B).
- 12. In early 2016, Proove fell significantly behind in payments purportedly owed to PMA. NSPC and PMA personnel had multiple exchanges with Proove inquiring as to the status of payment. Internally, NSPC and PMA personnel discussed potential "warning shot[s]" they could send to Proove in response to the non-payment, including halting testing for a week or stopping expansion of the Proove program into new offices, the latter of which was subsequently communicated to Proove. Proove's CEO responded, in part, by communicating that NSPC's "reduction in volume" in Proove testing was "completely unacceptable" and that if NSPC "could spend a little more time working on performance and volume, everything would work more effectively."
- 13. As a result of Anti-Kickback Statute violations, Medicare overpaid Proove for claims submitted in connection with Proove's contract with PMA. Proove paid PMA \$1.1 million over the course of the PSA. NSPC understands that Medicare paid Proove a total of approximately \$4 million for claims submitted in connection with Proove's contract with PMA.
- 14. Due to compliance concerns that were identified in the course of due diligence review by the now current owners of NSPC, the contract with Proove was terminated on March 3, 2017, prior to the acquisition of NSPC by a new ownership group.

## **EXHIBIT B**

## **WAIVER OF INDICTMENT**

In the event that the United States Attorney's Office for the Central District of California institutes a criminal prosecution against National Spine and Pain Centers, LLC, following a determination of a breach of the Non-Prosecution Agreement, in accordance with paragraphs 12 through 14 of that Agreement, National Spine and Pain Centers, LLC, having been advised by counsel of its rights and the nature of potential charges arising out of the Statement of Facts, waives its right to indictment and agrees that criminal proceedings may be by information rather than indictment for any federal offense arising out of the Statement of Facts attached as Exhibit A to the Non-Prosecution Agreement.

DocuSigned by:
National Spine and Pain Centers, LLC
by: Neil Kunkel, Chief Legal Officer

PATRICK COLLINS

King & Spalding LLP Counsel for National Spine and Pain Centers, LLC 8/3/2021

DATE

8/3/2021

DATE

#### **EXHIBIT C**

### **COMPANY OFFICER'S CERTIFICATE**

I have carefully reviewed every part of this Agreement, including Exhibits A-E, with outside counsel for National Spine and Pain Centers, LLC ("NSPC"). I understand the terms of this Agreement and voluntarily agree, on behalf of NSPC, to each of its terms. Before signing this Agreement, I consulted with outside counsel for NSPC. Counsel fully advised me of the rights of NSPC, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of NSPC, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Chief Legal Officer for NSPC and that I have been duly authorized by NSPC execute this Agreement on behalf of NSPC.

National Spine and Pain Centers, LLC by: Neil Kunkel, Chief Legal Officer

8/3/2021

DATE

#### **EXHIBIT D**

# **CERTIFICATE OF COUNSEL**

The undersigned is counsel for National Spine and Pain Centers, LLC in the matter covered by this Non-Prosecution Agreement. In connection with such representation, I have examined relevant company documents and have discussed the terms of this Non-Prosecution Agreement with Management for National Spine and Pain Centers, LLC. Based on my review of the foregoing materials and discussions, I am of the opinion that Neil Kunkel is duly authorized to enter into this Non-Prosecution Agreement on behalf of National Spine and Pain Centers, LLC, and that this Non-Prosecution Agreement has been duly and validly authorized, executed, and delivered on behalf of National Spine and Pain Centers, LLC, and is a valid and binding obligation of National Spine and Pain Centers, LLC. Further, I have carefully reviewed the terms of this Non-Prosecution Agreement with Mr. Kunkel. I have fully advised him of the rights of National Spine and Pain Centers, LLC, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Non-Prosecution Agreement. To my knowledge, the decision of National Spine and Pain Centers, LLC to enter into this Non-Prosecution Agreement, based on the authorization of the Chief Legal Officer of National Spine and Pain Centers, LLC, is informed and voluntary.

PATRICK COLLINS

King & Spalding LLP

Counsel for National Spine and Pain Centers, LLC

8/3/2021

DATE

#### **EXHIBIT E**

### **Medicare Restitution Payment Submission Instructions**

To wire funds to CMS, please provide your financial institution with the following information. All of this information must be included in the wire instructions sent forward to the New York Federal Reserve Bank.

Subtype/Type Code – 10 00

Amount - \$5,100,000

Sending Bank Routing Number - Fill in

Receiver Financial Institution (Routing Number for Treasury NYC) – 021 030 004 Receiver Name – Treasury NYC Receiver Address – 33 Liberty Street, New York, NY 10045

Beneficiary Account Number (CMS Agency Location Code) – 875050080000 Beneficiary Name – Centers for Medicare & Medicaid Services (CMS) CMS tax ID number – 52-0883104

Optional Field Remarks – Restitution from National Spine and Pain Center re Proove Biosciences; CMS contact Veronica Moore, tel. 410-206-4133.

Federal Reserve Assistance Number – (212) 720-6130