IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

American Association of Nurse Anesthetists and Lisa Pearson, CRNA, NSPM-C, DAPPM	)	
Plaintiffs,	)	Case. No.: 17-CV-2753
v.	)	
Novitas Solutions, Inc., and Seema Verma, *in her official capacity as* Administrator of the Centers for Medicare and Medicaid Services,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

The American Association of Nurse Anesthetists (the "AANA"), representing the interest of this country's over 50,000 Certified Registered Nurse Anesthetists ("CRNAs"), and Lisa Pearson, CRNA, NSPM-C, DAPPM ("Lisa Pearson" and, together with the AANA, "Plaintiffs"), through their undersigned counsel, seek both declaratory and injunctive relief from this Court. For their Complaint against the defendants Novitas Solutions, Inc. ("Novitas") and Seema Verma, in her offical capacity as Administrator of the Centers for Medicare and Medicaid Services ("CMS" and, with Novitas, "Defendants"), Plaintiffs allege as follows:

NATURE OF THE CASE

1. This is an action for a temporary restraining order, preliminary injunction, and declaratory relief to prevent Defendants' unlawful and improper rulemaking and, thus, to prevent the deprivation of Plaintiffs' protected rights without proper due process. Moreover, it will prevent vulnerable populations from losing access to care and being severed from their chosen healthcare providers.

2. CMS, in 2012, engaged in proper rulemaking under the Administrative Procedure Act (the "APA"), 5 U.S.C. § 500 *et seq*., and clarified the regulation, 42 C.F.R. § 410.69, providing that CRNAs will be reimbursed for anesthesia and related care and that the related care includes chronic pain management care where the performance of that care is allowed by the scope of practice of the state in which the services are performed. Thus, CMS created a protected property interest in reimbursement for CRNAs.

3. On May 4, 2017, however, a local coverage determination propounded by Novitas will go into effect that will, in essence, foreclose CRNAs from being reimbursed for their treatment of Medicare beneficiaries suffering from chronic pain.

4. Novitas, however, exceeds its authority by seeking to change a "substantive legal standard," a power reserved only for CMS and the proper rulemaking procedures set forth in the APA.

5. As a result, CRNAs are foreclosed from any meaningful challenge to this improper rulemaking and are, thus, deprived of their constitutionally protected due process.

6. If this conduct is permitted to move forward, many CRNAs, like Dr. Pearson, who, in reliance on the federal rulemaking, have built entire practices around treating patients with chronic pain, will be foreclosed from meaningful participation in Medicare.

7. Moreover, if CRNAs are foreclosed from meaningful participation in Medicare, vulnerable populations, such as rural communities, military veterans, troops in combat, senior citizens, and those suffering from chronic pain, will be deprived of access to quality care.

THE PARTIES

8. The AANA, established in 1931, is the professional association for CRNAs and student registered nurse anesthetists ("SRNAs"), and AANA membership includes more than

50,000 CRNAs and SRNAs, over 90 percent of the nurse anesthetists in the United States.

9. Lisa Pearson is a CRNA, a member of the AANA, and a citizen of Colorado. She is also a Diplomate of the American Academy of Pain Management and is Nonsurgical Pain Management Certified by the National Board of Certification and Recertification for Nurse Anesthetists ("NBCRNA").

10. Medicare is a federal health care program existing pursuant to and operating in accordance with 42 U.S.C. Subchapter XVIII and its associated regulations. Medicare primarily serves elderly individuals and individuals with certain qualifying disabling conditions.

11. CMS is the federal agency that administers the Medicare program.

12. Defendant Seema Verma is the Administrator of CMS and is sued in her official capacity. As the Administrator of CMS, she is responsible for the development and implementation of the unlawful conduct of CMS' agent, Novitas, challenged in this action.

13. Novitas Solutions, Inc., a Pennsylvania corporation, is a Medicare Administrative Contractor ("MAC"). A MAC is a private health care insurer that has been awarded a geographic jurisdiction to process and administer Medicare Part A and Part B medical claims for Medicare beneficiaries. CMS relies on a network of MACs to serve as the primary operational contact between the Medicare program and the health care providers enrolled in the program.

JURISDICTION AND VENUE

14. This action arises under the Due Process Clause of the Fifth Amendment to the United States Constitution and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

15. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

16. Venue is proper in this District under 28 U.S.C. § 1391(e).

FACTS GIVING RISE TO THE AANA'S COMPLAINT

Anesthesia and Chronic Pain Management

17. Administration of anesthesia involves a temporary, induced loss of sensation and/or awareness for purposes of facilitating surgical and other invasive procedures. Anesthesia is used in a variety of settings, including hospital surgical suites, obstetrical delivery rooms, non-operating room anesthetizing locations, ambulatory surgical centers, pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons and proceduralists. Anesthesia care also involves pain management related to procedures (acute pain management) and chronic pain management that may be a consequence of inadequate acute pain management, injury, or other diseases.

18. Administration of anesthesia is a unique component of the healthcare delivery system because, when performed by a physician, it constitutes the proper practice of medicine, and, when performed by a CRNA, it constitutes the proper practice of nursing.

19. The practice of chronic pain management is a growing field in healthcare and in anesthesia. According to a study published by the Institute of Medicine of the National Academies in 2011, one hundred million Americans suffer from chronic intractable pain that costs $635 billion each year in medical treatment and lost productivity. With an aging population, those numbers are only expected to rise.

20. The United States, however, is suffering from a critical shortfall of practicing pain physicians, with the current number being estimated at 3,000 to 4,000. Virtually none of those physicians work among rural and military populations, leaving those populations vulnerable and without reasonable access to care.

21. CRNAs are educated and possess clinical experience in regional anesthetic

techniques, including patient selection, insertion, and management of regional blocks. This includes the introduction of medication and other agents into the epidural space ("Epidurals"). The epidural space is the outermost structure of the spinal canal. It runs the length of the spine and, in addition to traversing nerves, contains fatty tissue and blood vessels. Epidurals are placed by CRNAs on a daily basis across the country in a variety of healthcare settings for surgical anesthesia, labor analgesia and anesthesia, and acute and chronic pain management.

22. Chronic pain management, especially for spinal disorders, is often treated through image-guided Epidural steroid injections. Life changing, significant, and disabling pain can occur as a result of anatomic changes, irritation, inflammation, or injury to a spinal nerve root.

23. In the context of pain management, the use of imaging guidance has been shown to enhance the accuracy and safety of needle placement for all Epidurals.

Role of CRNAs

24. Nurse anesthetists have provided anesthesia in the United States for over 150 years. They are educated and clinically prepared to be autonomous providers of anesthesia.

25. Today, CRNAs are advanced practice registered nurses who personally administer more than 43 million anesthetics for patients each year in the United States. They administer anesthesia in every healthcare setting in which anesthesia services, resuscitation, or the management of pain is required.

26. Importantly, CRNAs also fill in the critical shortfall by providing access to care to underserved urban and rural communities where otherwise there would be no access to anesthesia. In these communities, without CRNAs, there would be no access to anesthesia and chronic pain management services.

27. CRNAs work in every setting in which anesthesia is delivered. They provide

epidural analgesia and anesthesia for mothers during childbirth. Anesthesia services provided by CRNAs are also a major component of care in veterans' hospitals, and CRNAs are most often the only anesthesia professional in Forward Surgical Teams to resuscitate, stabilize, and provide initial anesthesia and acute pain management for transportation of military personnel wounded in front-line combat.

28. In many rural areas, CRNAs often are the only health care professionals educated and prepared to lead and provide comprehensive 24/7 anesthesia services. In these communities, patients rely on care from a CRNA in their local community because they are unable to travel long distances for care. Without CRNAs to administer anesthesia and related services, Medicare beneficiaries in vast rural and frontier areas would lose access to vital treatment, which could result in poor healthcare outcomes, lower quality of life, and unnecessary costs to patients, Medicare, and the healthcare system. It would also result in leaving patients to otherwise manage or endure their chronic pain.

29. Epidurals are but one of many regional nerve blocks in which CRNAs are educated, and the administration of Epidurals is a routine part of CRNA practice. To assist in their treatment, CRNAs often use imaging services in conjunction with providing chronic pain management services to patients. For example, CRNAs frequently employ fluoroscopy as an adjunct to pain management diagnostic and therapeutic procedures, consistent with state law. These imaging techniques have improved the safety of pain management for patients by eliminating the "blind" component of technical care allowing for precise needle positioning and accurate placement of medications in targeted areas for best results.

30. The various procedures that encompass chronic pain management services are within the CRNA scope of practice, and CRNAs are only prohibited from performing pain

management services in one state.

31. There are CRNAs whose practice offers chronic pain management services that are provided separate and distinct from surgical anesthesia and acute pain management.

32. For example, Dr. Pearson owns and operates two pain clinics in the state of Colorado, one of which is in a retirement community. Her services include medication management and interventional therapy, such as the administration of Epidurals. She employs two other CRNAs and 12 support staff. Her clinics provide care for a significant number of Medicare beneficiaries.

Education of CRNAs

33. Chronic pain management lies along the continuum of anesthesia care that CRNAs are educated on and qualified to provide.

34. The Council on Accreditation of Nurse Anesthesia Educational Programs ("COA") standards mandate that nurse anesthesia programs provide content in, but not limited to, anatomy, physiology, pathophysiology, pharmacology, and acute and chronic pain management. Similarly, the COA requires that nurse anesthesia students obtain clinical experiences in regional anesthetic techniques (*i.e.*, spinal, epidural, and peripheral) and experiences in managing patients with acute and chronic pain. Nurse anesthesia education, clinical practice experience, and skill development to practice pain management are core elements of nurse anesthesia education programs.

35. CRNAs further develop their expertise through multiple routes, including, but not limited to, formal fellowships, informal fellowships, observation and direct supervised practice, continued education, anatomic dissection labs, specialty workshops, and practicums in imaging and radiation safety.

36. All CRNAs are certified and recertified to practice by an accredited nationally recognized organization, the NBCRNA.

37. The NBCRNA further offers a nonsurgical pain management subspecialty certification for CRNAs. The AANA has partnered with academia to develop an Advanced Chronic Pain Management Fellowship that is accredited by the COA to enter the field as advanced, subspecialty practitioners beyond that required for initial certification of nurse anesthetists.

38. The formal requirements to become a CRNA include:

a. A Bachelor of Science in Nursing or other appropriate baccalaureate degree;
b. A current license as a registered nurse;
c. At minimum of one year of experience as a registered nurse in a critical care setting;
d. Graduation with a minimum of a master's degree from an accredited nurse anesthesia educational program; and
e. Successful completion of the national certification examination following graduation.

39. For example, Dr. Pearson is a CRNA and has received her doctorate in nurse anesthesia practice. She is a Diplomate of the American Academy of Pain Management. She is also certified under the NBCRNA subspecialty certification program and in fluoroscopy by the American Association of Physicists in Medicine.

40. Any claim that CRNAs are not educated to perform the procedures that constitute the management of chronic pain is patently false. This is particularly evident when considering that the specific regional block at issue, the administration of an Epidural, is performed by CRNAs on a daily basis throughout the country and in every healthcare setting in which it is required.

Statutory and Regulatory Framework

Reimbursement

41. The Omnibus Budget Reconciliation Act ("OBRA") of 1986 authorized direct reimbursement of CRNA services under Medicare Part B beginning in 1989. 42 U.S.C. § 1395 l(a)(1)(H); 42 U.S.C. § 1395 x(s)(11).

42. It goes on to clarify that CRNA services refer to "anesthesia services and related care furnished by a certified registered nurse anesthetist . . . which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished." 42 USCS § 1395x (bb).

43. Accordingly, the Code of Federal Regulations states that "Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished." 42 CFR 410.69(a).

44. As set forth above, various procedures that encompass chronic pain management services are within the CRNA scope of practice, and CRNAs are only prohibited from performing pain management services in one state.

Rulemaking

45. The federal rulemaking procedures are governed by the APA at 5 U.S.C. §553. Generally, the APA's rulemaking provisions require CMS and other agencies to go through three steps to enact substantive rules: notice of the proposed rule, a hearing or receipt and consideration of public comments, and the publication of the new rule. Further, Section 553(e) gives all interested parties the right to appeal and challenge a rule. 42 U.S.C §1394hh(2) clarifies that only an agency such as CMS may establish a rule that "changes a substantive legal standard

governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits . . . ."

46. In contrast, MACs such as Novitas are authorized to promulgate local coverage determinations ("LCDs"). An LCD is a decision by a MAC as to whether to cover a particular item or service on a MAC-wide basis; they specify under what clinical circumstances an item or service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. LCDs must be consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

47. In promulgating an LCD, MACs must provide for both a comment period and a notice period, but only beneficiaries are permitted to appeal and challenge an LCD.

Prior Efforts to Block CRNAs from Reimbursement

48. MACs have a history of attempting to block reimbursement to CRNAs for pain management. Despite Medicare's long track record for directly reimbursing CRNAs, in 2011, two separate MACs, Wisconsin Physician Services Insurance Corporation ("WPS") and Noridian Healthcare Solutions ("Noridian"), issued policies denying direct reimbursement of CRNA chronic pain management services.

49. A storm of disagreement ensued as to whether CRNAs should be reimbursed for the provision of pain management services, and CMS engaged in the rulemaking process to amend 42 C.F.R. 410.69 to its current version, thereby addressing that issue. As a result of the rulemaking, CMS requires reimbursement for any CRNA service authorized by the law of the state in which the services are furnished, which includes pain management services.

50. CMS specifically stated that it considered issues of health and safety in propounding the new rule and that it considered pain management part of the scope of its

analysis.

51. Ultimately, CMS left the determination regarding the inclusion of pain management to the state scope of practice standards.

52. Since the passage of this rule, and in reliance upon this federal regulation, CRNAs, like Lisa Pearson, have developed pain management practices and incorporated pain management into their business models.

Novitas' Current Improper Conduct

53. Novitas now seeks to block proper reimbursement for CRNA pain management services through improper rulemaking. It is attempting to do so by propounding Future Local Coverage Determination L36920: *Epidural Injections for Pain Management* ("L36920"), which is set to go into effect on May 4, 2017. *A true and correct copy of L36920 is attached as Exhibit A.*

54. Purportedly based on patient safety, in order to be reimbursed for Epidural chronic pain treatment, a provider's training

> [M]ust cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, proficiency in diagnosis and management of disease necessitating the procedures, the technical performance of the procedure with utilization of the required associated imaging modalities, as well as the diagnosis and management of potential complications from the intervention.

55. It goes on to set out the only four paths through which a provider may demonstrate acceptable training:

a. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) accredited residency and/or fellowship program in a relevant specialty (e.g., Interventional Pain Management, Anesthesiology).

b. Board certification in relevant specialty by an American Board of Medical Specialties (ABMS) member board or equivalent AOA

board.

c. Satisfactory completion of substantially equal training via an accredited non-physician practitioner educational program that renders the trainee eligible to sit for a non-physician practitioner licensing examination that directly assesses trainee competence to perform services included in this policy. The core curriculum of such programs must include the performance and management of the procedures addressed in this policy with documentation of assessment by examination.

d. Satisfactory performance and reporting to Medicare for payment of the specific interventional pain management services in this policy on a regular basis over the five years immediately preceding implementation of this policy. Medicare considers an average of ten services per month to meet this requirement as demonstrated by Medicare claim history.

56. In addition, it requires formal licensing or certification for imaging techniques related to Epidurals.

57. Finally, the LCD notes that "Novitas is not aware of any available training/certification programs for non-physician practitioners that would enable them to meet the stated requirements."

58. Thus, L36920 provides a path for CRNAs that leads nowhere. It excludes them from reimbursements that they are specifically authorized to receive. For CRNAs whose practices are reliant upon the reimbursement generated by the performance of these procedures, it acts as a *de facto* revocation from participation in the Medicare Program.

59. As set forth above, only proper rulemaking under the APA and through CMS, with its attendant protections and rights to challenge, is entitled to change "a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits . . . ."

60. Novitas is authorized to issue a proper LCD. However, in propounding L36920,

Novitas has exceeded its proper authority and trespassed into CMS's rulemaking power. Moreover, they have done so without going through the proper rulemaking process.

61. Further, its rationale is pretextual. CRNAs education and experience fulfill the categories of training requirements set forth in L36920, but, inexplicably, their certification is not included in the list of acceptable evidence of training.

62. In determining the best course of action was to defer to the scope of practice standards established by each individual state, CMS already considered patient safety in propounding the amendment to 42 C.F.R. 410.69 that authorized reimbursement.

63. Through LCD L36920, Novitas is, in effect, independently, improperly, and arbitrarily redefining the scope of practice of CRNAs.

64. Moreover, researchers studying anesthesia have found no measurable difference in the quality of care or in patient outcomes between CRNAs and physician anesthesia providers. Rather, they have found that incidents occur because of a lack of attention or underlying patient comorbidities, not from a lack of or difference in education.

Irreparable Harm

65. If L36920 is permitted to go into effect, the AANA and its members will suffer irreparable harm to their livelihoods. Many CRNAs, like Dr. Pearson, in reliance on the federal rulemaking, have built entire practices around chronic pain management. L36920 will effectively foreclose them from participation in Medicare.

66. In addition, because Novitas engaged in improper rulemaking, the AANA and its members have been deprived of any ability to challenge the validity of this *de facto* rulemaking. Plaintiffs' only recourse is to challenge Novitas' improper rulemaking before this Court.

67. Most importantly, if CRNAs are foreclosed from meaningful participation in

Medicare, vulnerable populations, such as rural communities, military veterans, troops in combat, and those suffering from chronic pain will be deprived of access to care.

COUNT I
Due Process of Law
U.S. Const. Amend. V

68. The allegations contained in paragraphs 1 through 68 above are incorporated by reference as if fully set out herein.

69. Under section 1881 of the Social Security Act and the related statutory scheme, including 42 C.F.R. §§ 410.12 and 410.69, CRNAs have a constitutionally protected property interest in receiving Medicare payments for anesthesia services and related care, including the administration of Epidurals for pain management, when authorized by the state in which the services are performed.

70. Defendants' use of the LCD process to deprive CRNAs of their constitutionally protected property interest without a hearing before an impartial decision-maker or a meaningful right to appeal violated their rights under the Due Process Clause of the Fifth Amendment.

71. The procedures used by Defendants to deprive CRNAs of their property interest were constitutionally inadequate because they did not allow CRNAs to participate in a hearing or in a meaningful appeal process before depriving them of a property interest that was established by law, is protected by the Constitution, and on which many CRNAs rely for their livelihood.

72. Defendants have also violated CRNA's right to Due Process by promulgating an LCD that is arbitrary and capricious and inconsistent with the federal regulations governing Medicare reimbursement of CRNAs.

COUNT II
28 U.S.C. § 2201
Declaratory Judgment

73. The allegations contained in paragraphs 1 through 73 above are incorporated by reference as if fully set out herein.

74. An actual and substantial controversy exists between the Plaintiffs and Defendants as to their respective legal rights and duties. The Plaintiffs contend that Defendants' promulgation of the LCD is an improper attempt at rulemaking and violates their Due Process.

75. Defendants, on the other hand, presumably believe the LCD rightfully limits CRNAs' ability to obtain Medicare payments for anesthesia services and related care, including the administration of Epidurals for pain management. Accordingly, declaratory relief pursuant to 28 U.S.C. § 2201 is appropriate.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully requests that this Court:

(a) Declare that section 1881 of the Social Security Act and the related statutory scheme, including 42 C.F.R. § 410.69, creates a constitutionally protected property interest in CRNAs to continue receiving Medicare payments for anesthesia services and related care, including the administration of Epidurals for pain management;

(b) Declare that CRNAs are entitled to additional Due Process, including, but not limited to, a hearing before an impartial decision-maker and a meaningful appeal process, before their protected property interest can be deprived;

(c) Declare that the LCD is an improper attempt at rulemaking and that, by promulgating it, Defendants have exceeded their limited authority to make Medicare coverage determinations;

(d) Issue a temporary restraining order, pursuant to Fed. R. Civ. P. 65(c), prohibiting Defendants from further promulgating, finalizing, implementing, or enforcing the LCD as it relates to CRNAs, pending resolution of CRNAs' Due Process claims;

(e) Issue a preliminary and permanent injunction prohibiting Defendants from taking further action to limit or deprive CRNAs of their protected property interest in receiving Medicare payments for anesthesia services and related care, including the administration of Epidurals for pain management;

(f) Issue a mandamus directing Defendants to continue paying CRNAs for anesthesia services and related care, consistent with 42 C.F.R. §410.69, including the administration of Epidurals for pain management;

(g) Award the Plaintiffs its costs and fees, including reasonable attorney's fees related to this action; and

(h) Grant such other and further relief as this Court deems reasonable and just.

Dated: April 11, 2017

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that, on April 11, 2017, I filed the foregoing document via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Mark J. Silberman