

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

January 13, 2010

Donald D. Lanese, D.O.
155 W. Main Street, #1904
Columbus, OH 43215

RE: Case No. 09-CRF-031

Dear Doctor Lanese:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of Patricia A. Davidson, Attorney Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on January 13, 2010, including motions approving and confirming the Findings of Fact and Conclusions of the Hearing Examiner, and adopting an amended Order.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal must be taken to the Franklin County Court of Common Pleas.

Such an appeal setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of an original Notice of Appeal with the State Medical Board of Ohio and a copy of the Notice of Appeal with the Franklin County Court of Common Pleas. Any such appeal must be filed within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12, Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO



Lance A. Talmage, M.D.
Secretary

LAT:jam
Enclosures

CERTIFIED MAIL NO. 91 7108 2133 3936 3068 2672
RETURN RECEIPT REQUESTED

Cc: Gerald T. Sunbury, Esq.
CERTIFIED MAIL NO. 91 7108 2133 3936 3068 2696
RETURN RECEIPT REQUESTED

Elizabeth Y. Collis, Esq.
CERTIFIED MAIL NO. 91 7108 2133 3936 3068 2719
RETURN RECEIPT REQUESTED

Mailed 2-12-10

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of Patricia A. Davidson, State Medical Board Attorney Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on January 13, 2010, including motions approving and confirming the Findings of Fact and Conclusions of the Hearing Examiner, and adopting an amended Order; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of Donald D. Lanese, D.O., Case No. 09-CRF-031, as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.



Lance A. Talmage, M.D.
Secretary

(SEAL)

January 13, 2010
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

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CASE NO. 09-CRF-031

DONALD D. LANESE, D.O.

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ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on January 13, 2010.

Upon the Report and Recommendation of Patricia A. Davidson, State Medical Board Attorney Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the modification, approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that no further action shall be taken in the matter of Donald D. Lanese, D.O.

This Order shall become effective immediately upon the mailing of notification of approval by the Board.

(SEAL)



Lance A. Talmage, M.D.
Secretary

January 13, 2010

Date

2009 DEC 17 PM 4: 38

BEFORE THE STATE MEDICAL BOARD OF OHIO

In the Matter of

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Case No. 09-CRF-031

Donald D. Lanese, D.O.,

*

Hearing Examiner Davidson

Respondent.

*

REPORT AND RECOMMENDATION

Basis for Hearing

In a notice of opportunity for hearing [Notice] dated March 11, 2009, the State Medical Board of Ohio notified Donald D. Lanese, D.O., that it intended to determine whether or not to take disciplinary action with regard to his certificate to practice osteopathic medicine and surgery in Ohio. The Board made allegations including that Dr. Lanese, a radiologist, had failed to note the presence of a metallic fragment in reading and/or interpreting radiographs of a patient's foot. The Board also alleged that Dr. Lanese had admitted to handling about 2,000 cases per week, reading about 30 radiographs per hour, and working 12 to 13 hours per day, four to five days per week. (St. Ex. 1A)

The Board charged that Dr. Lanese's alleged acts, conduct, and/or omissions, individually and/or collectively, constitute a "departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that language is used in Ohio Revised Code Section [R.C.] 4731.22(B)(6). (St. Ex. 1A)

The Board received Dr. Lanese's request for hearing on March 18, 2009. (St. Ex. 1B)

Appearances

Richard Cordray, Attorney General, and Barbara J. Pfeiffer, Assistant Attorney General, for the State. Gerald T. Sunbury, Esq., and Elizabeth Collis, Esq., for the Respondent.

Hearing Date: September 22, 2009

SUMMARY OF THE EVIDENCE

All exhibits and the transcript, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

Background Information

1. Donald D. Lanese, D.O., was born in Ohio in 1938 and received his degree in osteopathic medicine in 1964 from the Kirksville College of Osteopathic Medicine in Missouri. He testified that after a year of internship at Green Cross Hospital in Cuyahoga Falls, Ohio, he trained for

two years at Cuyahoga Community Hospital in Akron and then a year at the Art Centre Hospital in Detroit, Michigan, during which time he also obtained six months of mammography training at Hutzel Women's Hospital in Detroit. Dr. Lanese noted that the Art Centre Hospital in Detroit received many cases involving traumatic injuries, stabbings, and gunshots. Dr. Lanese received his Ohio license, number 34.001528, in 1965. (St. Ex. 6 at 10-12; Tr. at 162-164; Ohio eLicense Center at <<https://license.ohio.gov/lookup/default.asp?division=78>>, Nov. 18, 2009)

2. Dr. Lanese testified that, after his training, he headed the radiology department at Mary Rutan Hospital in Bellefountaine, Ohio, beginning in 1970. In 1974, Dr. Lanese formed a professional corporation, Spectrum Radiology, which is located at his home address in Columbus, Ohio. He started doing private consulting work as Spectrum Radiology in 1974, in addition to his hospital work. Dr. Lanese then left Mary Rutan Hospital in 1976 to work full-time in his private consulting business. He has one employee, a secretary, and also employs a doctor on a contract basis to work for the corporation on Fridays and Saturdays. (St. Ex. 6 at 10-17, 22-24; Tr. at 160-166, 188, 206-209)
3. Dr. Lanese stated in his interrogatory answers that he is licensed to practice medicine in Michigan, Kentucky, Wisconsin, Indiana, Illinois, Maryland, and Kansas. (St. Ex. 5 at 6) During his deposition, he stated that he is also licensed in Massachusetts, Connecticut, and New Hampshire. Dr. Lanese also reads x-rays transmitted from states that do not require him to hold an active license in those states to receive and interpret images in Ohio as a teleradiologist. Dr. Lanese testified that he has never been investigated by any other medical board or any hospital, has never had hospital privileges suspended or limited, and has not otherwise been reprimanded or disciplined by an employer, hospital, or licensing authority. (Tr. at 160-166, 188, 208-209; St. Ex. 6 at 10-16)
4. Dr. Lanese testified that has worked as an independent contractor for MobilexUSA [Mobilex] since about 1996, providing medical services as a teleradiologist. Mobilex employs x-ray technicians at various institutions, such as prisons and nursing homes, and it digitizes the images taken by the technicians and transmits them electronically to radiologists in various states who read and interpret them using a computer system. Dr. Lanese also reviews and interprets x-rays for several general-practice clinics, which he has been doing since 1974. (St. Ex. 5, Resp. Ex. D; St. Ex. 6 at 13, 17, 20-21, 25, 27-29; Tr. at 160-169, 174-175)
5. With regard to his use of certain terms, Dr. Lanese stated that the term "radiograph" is synonymous with "x-ray." He further testified that Mobilex compensated him by "the piece," which means he was paid per each "case" or "study." He explained that one case or study involves one body part but may involve multiple views of that body part. Thus, three x-ray views of the same hand would constitute one case or study. Likewise, if there were two different views of the same chest, that would be one case or study. In contrast, if there are views of a chest and an abdomen of the same patient, that would constitute two cases. (St. Ex. 6 at 19, Tr. at 186)

The Subject X-Rays & Dr. Lanese's Radiology Report

6. On or about July 26, 2006, Mobilex electronically transmitted to Dr. Lanese a radiographic study consisting of a group of three views of the left foot of Patient 1. In addition, Dr. Lanese was given the patient's age (17 years old), facility (a juvenile corrections facility), the reason for the x-ray study (pain in the foot), and the referring physician's name. (St. Ex. 2, Tr. at 194-195; St. Ex. 6 at 35-36)¹
7. After he reviewed the x-ray study, Dr. Lanese provided a verbal report, stating that the x-ray study of the left foot was "negative." He also generated a written report (St. Ex. 2, second page), in which he stated:

Date of service: 07/26/2006

Examination:

LEFT FOOT: Routine views of the left foot reveal no evidence of fracture, dislocation, or other significant bone or joint abnormality. Cortical and trabecular markings are unremarkable.

IMPRESSION:

1. No acute bony or joint abnormality.

8. It is undisputed that the patient had a bullet fragment in his left foot and that this foreign body is visible in the x-ray study, especially the lateral view. It is undisputed that Dr. Lanese's reading of the x-ray study was erroneous. (Resp. Ex. B; St. Ex. 8; St. Exs. 3-4; St. Ex. 6 at 40; Tr. at 37-39)
9. Dr. Lanese was asked to reread the x-rays of Patient 1's foot. On August 9, 2006, he performed a second reading of the x-ray study of Patient 1's foot, and reported as follows:

REREAD BY DONALD LANESE D.O. ON 08/09/06

There is a bullet fragment noted adjacent to the anterior superior border of the calcaneus.

(St. Ex. 2, second page)

10. Initially, when asked during his deposition whether his first reading of the x-ray was "incorrect," Dr. Lanese answered, "No." He explained that his statement in the first radiology report was correct in that there was no bony pathology shown in the x-ray. He acknowledged, however, that he "did not mention the bullet fragment." Subsequently, Dr. Lanese testified unequivocally, as follows: "Did I make an error? Yes." (St. Ex. 6 at 40, 42)

¹ The patient's name is recorded on a confidential patient key admitted under seal.

11. During the hearing, Dr. Lanese emphasized that his reading was “accurate” in that he stated the absence of a fracture, which was correct. However, he acknowledged that he “didn’t mention the fragments.”² (Tr. at 12, 195) When asked whether there was anything that he would do differently if reading this x-ray study today, Dr. Lanese answered: “I’m sure I would have said something different.” He was then asked more pointedly whether he “would have noticed the fragment,” and he answered, “I probably might have mentioned that.” Finally, when asked whether it was “a mistake not to do that,” Dr. Lanese answered, “Yes, it was.” (Tr. at 197-198)
12. During his deposition, Dr. Lanese admitted that, with regard to the metal shown in the x-ray study of Patient 1’s foot, he “missed that the first time around.” When asked why, he answered: “It got by me.” Dr. Lanese stated that he could not provide a reason or explain what had happened, as he did not specifically recall his reading of Patient 1’s film. Similarly, he did not recall what he was told when asked to reread the film or why he was asked to read it again.³ When asked whether his failure to note the metal was caused by reading the films too quickly, he stated: “I don’t know. I can’t give you an answer to that.” (Tr. at 178, 196-197; St. Ex. 6 at 40-41)

However, when asked during the hearing whether there was “any correlation” between his workload and his error with regard to Patient 1’s x-ray, Dr. Lanese answered, “No.” He asserted that his mistake had “nothing to do with the number of films I read that day.” He added: “I just don’t see the relationship there.” (Tr. at 205)

13. When asked whether there had been other instances when he had misread an x-ray, Dr. Lanese answered “yes,” but he stated that it happens “rarely.” He estimated at first that such errors occur about three times a year, but then thought further, and stated that it was more likely “10 times” per year, “when you figure I do 100,000 cases.” (St. Ex. 6 at 41-42) Dr. Lanese estimated that his rate of error in reading x-rays is “probably one percent, maybe.” (Tr. at 189)

Statements By Dr. Lanese Regarding His Radiology Practice in General

14. On November 20, 2007, Dr. Lanese provided sworn, written answers to interrogatories posed by the Board. Among other things, Dr. Lanese stated that he reads approximately 2000 x-rays per week. He stated that he spends 15 hours each day reading and/or interpreting x-rays. (St. Ex. 5)

²Dr. Lanese and the expert witnesses sometimes referred to a single fragment and sometimes referred to multiple fragments in their testimony and reports. Dr. Lanese testified that he had seen bullet “fragments” (plural) in the x-ray upon his second reading, although he also testified regarding the bullet “fragment” (singular) that was in the patient’s foot. His written radiology report refers to a single “fragment” that was seen upon re-reading. The Respondent’s expert noted a “foreign body” (singular) in his written report, but testified at hearing that he saw “fragments.” A review of the lateral x-ray itself shows one comparatively large body that is visible as a white irregular shape in the tissue near the calcaneus, with much smaller white dots nearby that are not as readily visible. (St. Ex. 6 at 40; St. Exs. 2, 3, 4, 8; Resp. Ex. B; Tr. at 37-39, 112)

³Although Dr. Lanese acknowledged that he learned of the error within two weeks, he noted that at least two years had elapsed between reading the x-ray and learning of the Board’s investigation of a potential disciplinary issue. (Tr. at 179)

15. In a 2008 deposition, Dr. Lanese testified that he averages about 2,000 cases a week *for Mobilex alone*. He discussed teleradiology, explaining how cases come to him from different areas of the United States. (St. Ex. 6 at 26) In addition, Dr. Lanese testified that he reads films for six or eight general-practice clinics in the Columbus area. (St. Ex. 6 at 20-21)
16. However, Dr. Lanese stated at the hearing that, during 2006, he was working for ten of these clinics. With regard to the volume of cases received from these clinics, there was very little evidence. Dr. Lanese testified at the hearing that there is “one urgent care center that still sends us plain films that's usually less than ten a day.” (Tr. at 27, 99)
17. During his deposition testimony, Dr. Lanese estimated generally that he reads about 30 radiographs per hour. (St. Ex. 6 at 30)
18. Dr. Lanese also testified that, although the amount of time per x-ray would vary, he estimated that he spent two to three minutes per x-ray. (St. Ex. 6 at 30, Tr. at 224-225)
19. Dr. Lanese testified that he generally reads only x-rays, mostly plain film radiographs of chests and spines. He stated that he does not do CT scans or MRIs although in the past he read mammograms, ten years ago before the malpractice insurance became too expensive. (St. Ex. 6 at 25-26; Tr. at 168)
20. Dr. Lanese testified that, when working for Mobilex, he works from 10:00 a.m. to 5:00 p.m. at the Mobilex offices in Worthington, Ohio, and then continues to work at his home office from 5:30 p.m. to 11:00 p.m. He stated that he works these hours for Mobilex four days per week, Monday through Thursday, and also works from 1:00 to 5:00 p.m. on Sundays. (St. Ex. 6 at 17, 27-29)
21. Dr. Lanese stated that Mobilex does not require him to work at home as well as the Mobilex office, but that it had been his own choice. When asked whether the hours might be “too much,” he answered: “Some days it is.” (St. Ex. 6 at 28)
22. With regard to his work for general-practice clinics, Dr. Lanese stated during his deposition that there are “six or eight” of them, and that he has worked for some of them since 1974, and that one of the clinics is in Akron. He stated that he visits the local clinics “a couple times a week” to read their x-rays, although urgent-care centers bring their films to him. In addition, some clinics send him films by Fed Ex delivery. (St. Ex. 6 at 20-21; Tr. at 166-169)

Opinion of the State’s Expert Witness

23. Diane H. Anderson, D.O., testified as an expert witness in diagnostic radiology. (Tr. at 16-82) She is board-certified in diagnostic radiology by the American Board of Radiology and has practiced in Ohio since 1996, in both a hospital setting and private practice. Her background, employment and training, including four years of residency at the Cleveland Clinic Foundation from 1991 to 1995, are set forth in more detail in her curriculum vitae (St. Ex. 7) and testimony at hearing. (Tr. at 16- 25)

24. Dr. Anderson described the PAC System used by radiologists (Picture Archiving and Communications System), which stores images and allows the radiologist to read them on a monitor. Almost all of her readings are done on a computer screen that shows digital images. She explained that one can manipulate the images, invert them, magnify them, and clarify them. For example a burned-out area can be made clearer. She also stated that using the system is “also a lot quicker” because one is not obliged to hang the films and take them down and put them in jackets. She explained that the copy of the x-ray provided on film as State’s Exhibit 3 is an “analog” or “plain film” x-ray. (Tr. at 25-29, 46)
25. In her written report and opinion, Dr. Anderson stated in pertinent part:

The radiographs provided were three views of the left foot, on one film. These appear to be copies of the original and are not the best images for fine bony detail. All three views clearly show metallic fragments in the soft tissues of the lateral foot.

In my professional opinion, to a reasonable degree of osteopathic radiological medical certainty, I believe that these metallic bullet fragments SHOULD have been mentioned on the radiologic written report. Although the underlying bone does not show any abnormalities, the foreign bodies are abnormal. In my professional opinion, Dr. Lanese failed to conform to minimal standards of care of similar practitioners under the same or similar circumstances.

In Dr. Lanese’s deposition, he indicated that he works approximately 56 hours a week and reads about 2,000 cases a week. This is well above the normal number of cases read by most radiologists. Reading this number of cases consistently hour after hour, day after day, week after week, in my opinion, is a situation that will lead to mistakes and missing important finding on x-rays.

In summary, in my professional opinion, to a reasonable degree of osteopathic radiological medical certainty, when Dr. Lanese interpreted Patient 1’s radiograph on or about July 26, 2006, he failed to conform to minimal standards of care of similar practitioners under the same or similar circumstances.

(St. Ex. 8)

26. At the hearing, Dr. Anderson testified in further detail regarding her opinions. She explained terms on Dr. Lanese’s radiology report, stating that “cortical markings” refer to the edge or cortex of the bone, and that “trabecular markings” are the inside of the bone. She agreed that the cortical and trabecular markings were unremarkable, as reported. (Tr. at 34)
27. However, Dr. Anderson testified that Dr. Lanese’s failure to note the metal fragments was a departure from the standard of care of similar practitioners under the same or similar circumstances. Upon request, she took a marker and wrote on the x-ray film to identify the oblique view, the AP (anterior posterior) view, and the lateral view of the foot, on a copy of Patient 1’s x-ray. In the lateral view, she pointed to what she described as “a large area and

then several smaller areas of white that are metallic density” in the soft tissue. (Tr. at 37-40; St. Ex. 3)⁴

28. Dr. Anderson stated that it would be common to receive no more history than “pain” in the x-rayed area, and that this happens often. (Tr. at 62)
29. Dr. Anderson testified that, when she reached her opinion, she had no information regarding whether there had been any harm to Patient 1 related to Dr. Lanese’s radiology report. (Tr. at 63)
30. With respect to the volume of cases, Dr. Anderson explained that there is no “technical norm” and that she is not aware of any limitations on the number of cases that a board-certified radiologist can review. However, she stated that Dr. Lanese handled more cases “than what most radiologists would read” and that 2,000 cases of x-ray studies per week is “excessive.” In forming her opinion, Dr. Anderson understood that each of the 2,000 cases handled by Dr. Lanese per week could involve multiple images. She explained that she considered the x-ray study of Patient 1’s foot to be one “case” with three “images.” (Tr. at 33, 53-54, 56, 76-77)
31. Dr. Anderson testified, with regard to the allegations in the Notice, that the facts as alleged in numbered paragraph 2 are correct.⁵ When asked whether those facts would constitute a departure from or failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, she responded:
 - A. My opinion is that the number of cases and the number of hours that Dr. Lanese admits that he works are more than normal, or more than what most radiologists would work.
 - Q. Okay. Do you consider that a failure to conform to, or a departure from minimal standards of care of similar practitioners under similar or same circumstances?
 - A. Yes.

(Tr. at 42-43)
32. With regard to her opinion regarding Dr. Lanese’s workload, Dr. Anderson reiterated the opinion in her written report. She stated that Dr. Lanese’s practice of regularly working the hours as

⁴This marked copy of Patient 1’s x-ray was admitted as State’s Exhibit 3. An unmarked copy was admitted as State’s Exhibit 4.

⁵In the second numbered paragraph in the Notice, the Board alleged as follows:

- (2) On or about February 12, 2008, you admitted that initially you did not correctly interpret the radiograph. You also admitted that you handle about 2,000 cases a week, working twelve to thirteen hours a day, four to five days a week. You also admitted that you read approximately 30 radiographs each hour and that you spend two to three minutes reading each radiograph.

stated creates “a situation that will lead to mistakes and missing important finding on x-rays.” (Tr. at 74)

33. Dr. Anderson stated that she generally works eight to nine hours a day, five days a week. She explained that the number of cases she completes in a day would depend on the type of cases. If she is reading only plain films on the PACS, then 150 or 200 cases would be her maximum, and 200 “is pushing it.” If she is reading mammographies and breast ultrasounds and doing procedures, the number of cases is about 100. If she is reading CT scans or MRIs, it is about 60 a day, because there are a lot more images on CTs and MRIs. She stated that these numbers would be the same for most of her partners. She stated that productivity statistics are published internally every six months, and that she is in the top half for productivity, closer to the top, not the middle. She stated that her compensation is not on a “per case” basis. (Tr. at 43-44)
34. Dr. Anderson further explained the number of images that are provided for different types of cases. For an ankle, she would see three. Four images is the standard for a mammography. A CT of the head might be 50 images. She has not counted the images for an abdomen/pelvis CT, but it might be 200 images. An MRI would depend on the body part and number of sequences, but could be several hundred. Dr. Anderson stated that when she said she would do 100 mammography readings in one day, she was referring to cases, not images. (Tr. at 47-48)
35. The issue arose as to whether residents would typically have a very high volume of cases. Dr. Anderson opined that radiologists would not read more cases during residency training. She explained that one reads fewer studies as a resident because a resident must consult with others about the interpretation of the images, and only then can the resident go back and dictate the report, so the “throughput is not as fast.” (Tr. at 53)
36. Dr. Anderson stated that if she sees something in an x-ray that is abnormal but “not significant,” she would still mention it in her report. (Tr. at 79)
37. Dr. Anderson described the quality-control program in her practice, which categorizes different levels of error, based in large part on a scale of patient harm, such as a “life threatening” omission or “incidental” omission. She acknowledged that she has been asked to reread a study when a physician calls and requests it. (Tr. at 65-68)
38. Dr. Anderson acknowledged that she did not know the exact number of cases that Dr. Lanese had handled on the day he read Patient 1’s x-ray.

Opinion of Dr. Lanese’s Expert Witness

39. Nicholas T. Peponis, D.O, testified as an expert witness in diagnostic radiology. He has been board-certified in diagnostic radiology by the American Osteopathic Board of Radiology since 1987 and has practiced in Ohio since 1987, specializing in neuroradiology. He works in a practice that “deploy[s] a radiologist as a full-time

equivalent for a day at a hospital.” Dr. Peponis has served as an associate clinical professor at Ohio University College of Osteopathic Medicine and served as the chair of the residency program. His background, employment and training are set forth in more detail in his curriculum vitae and his testimony. (Resp. Ex. A; Tr. at 96-104, 129-131)

40. In his written report and opinion, Dr. Peponis stated in pertinent part:

The examination, a 3 view x-ray study of the left foot dates 7-26-06 was accompanied by clinical indication of “pain in foot” as the only clinical information. The quality of the exam [the x-ray image] was average. The bony anatomy was appropriately interpreted as normal. A metallic foreign body in the soft tissues of the foot was later identified on a requested second viewing apparently prompted from the referring physician, after additional history of penetrating foreign body was provided. *It is my opinion that the foreign body could be seen, and the failure to identify on the first review clearly represented an error of perception.* Once additional clinical information was made available, Dr. Lanese correctly identified the foreign body.

Regarding the question of Dr. Lanese’s work hours discussed in his deposition, the number of hours, while considerable, is not out of line with the number of work hours of many busy clinical radiologists. In addition a portion of Dr. Lanese’s work hours are performed in his home setting, allowing for a more relaxed environment, mitigating to some degree the pressure of the workplace.

As to the number of “studies” Dr. Lanese interprets on a daily basis, this issue must be considered in light of the type of work he performs relative to other radiologic practitioners. The entirety of his case work is projection radiograms (x-rays), which he reads with the aid of a PACS system. The majority of the cases are 1 or 2 images. If an average of 2 images is assumed, at a daily volume of 400-500 cases, then he is viewing between 800 and 1000 images per day. In my general clinical practice in which I interpret 10–20 MRI, 15–25 CT exams, 10–15 ultrasound studies, and perhaps 50 x-rays studies, the number of exams does not equate. However when one considers that a typical MRI has 250 images, a typical CT 350 images, and ultrasound 50, then I might process between 8,000 and 15,000 images on a routine daily basis. Practitioners more engaged in sectional imaging may consider over 20,000 images a day. These volumes of images can only be evaluated utilizing computerized review, which allows for efficient through [sic] consideration of the images (PACS system). Because of these efficiencies, Dr. Lanese’s work load is clearly not out of line with current clinical practice with PACS support technology.

* * *

* * * This one case in and of itself would be inadequate criterion to establish that Dr. Lanese’s practice fails to conform to minimal standards of care. * * * It is my professional opinion that work hours, and load, though significant cannot be considered as outside the norm, and thus contributing factors.

(Resp. Ex. B) (emphasis added)

41. Further, Dr. Peponis stated that errors in radiology readings are not uncommon. He reported:

* * * Several studies have noted error rate for “significant” findings in the 5% range. [*sic*] Errors can be classified into subgroups including errors of knowledge, misperception, misinterpretation, anchoring bias, and even deficiencies of communication, amongst others.

(Resp. Ex. B) (citing “Alpert, H, Hill, B Quality and Variability in Diagnostic Radiology, J Am Coll Radiol 2004; 1:127-132”)

42. In addition, Dr. Peponis commented on the quality-control program at Mobilex, stating in part.

I have also learned that the Mobilex interpreting radiologists nationally participate in an internal second reading review process as part of the professional quality control.* * * While second readings are a relatively superficial approach to identifying practice quality outliers, they represent one of the best approaches available in radiology practices. * * *

(Resp. Ex. B)

43. At the hearing, Dr. Peponis stated that the amount of information provided to Dr. Lanese with the x-ray was the typical minimum information provided to radiologists. (Tr. at 110)

44. He also stated that Dr. Lanese’s initial impression was “correct” in that the x-ray showed no acute bony or joint abnormality. He noted that, in the supplemental report after the second reading, Dr. Lanese did not change anything but added an addendum. However, Dr. Peponis stated, as in his written report, that Dr. Lanese “erred by not mentioning the foreign body.” He also testified: “Again, I think you could call it an error. Yeah, call it an error.” When Dr. Peponis was asked whether, upon his own review of the patient’s x-ray, he had seen a bullet fragment, he answered: “There are metallic fragments in the tissue that one could assume was from a penetrating injury.” (Tr. at 111-113, 118, 120)

45. Dr. Peponis stated that, if he were reading Patient 1’s x-ray study and had information only that there was “pain in foot,” he probably would have described the bony structures as being intact and noted that “there was metal in the foot.” He indicated that, in the back of his mind, he would probably theorize that the metal in the patient’s foot could be a “potential source of pain.” However, Dr. Peponis noted that fragments are frequently asymptomatic. Dr. Peponis indicated the x-ray reader would not know, from the x-ray, when the fragments entered the tissue; the reader would not know whether the fragments had gotten into the tissue on the day before the x-ray was taken. (Tr. at 148-150)

46. When Dr. Peponis was asked whether Dr. Lanese “practiced below the standard of care by failing to note in his first report on July the 26th the metallic fragment in the foot,” he responded as follows:

A. I can't say that is necessarily the case. I can't say yes and I can't say no.

Having reviewed the case, having reviewed a lot of cases over the years that involved misdiagnoses in imaging, or errors, that it's always somewhat difficult to say is that a frank error.

There's a tremendous amount of variability in how images are interpreted, and errors have to be differentiated from variability in terms of what is considered, you know, in reporting. So, you know, is this within the realm of potential variability? It could be. * * *

* * *

Q. In your opinion, by failing to note the metallic fragment in the first read, do you believe that Dr. Lanese failed to conform to minimal standards of care?

A. The real answer is I don't know.

(Tr. at 114-115)

47. Dr. Peponis further testified that a radiologist is not required to describe "everything" he sees in an x-ray image. There are many findings that are of "no clinical significance," and one could "make a very elaborate report and talk a lot about nothing." (Tr. at 119)

48. Dr. Peponis was asked whether reading 2,000 cases per week, with each involving an average of one to three images, was an "excessive" number of x-ray cases for Dr. Lanese to be reviewing each week. He answered:

A. You know, I can't make that assessment if—I can say that it is a large number of cases, but it's not an impossible number of cases to be able to interpret.

Q. Do you believe that reviewing 2,000 cases a week falls below any type of rule or regulation that is -- exists for radiologist?

A. I don't know that. I don't know of anything that prohibits that.

Q. Based on the documents that you were given to review, the x-ray, and the x-ray report and the deposition and the interrogatory responses, do you believe that Dr. Lanese deviated from the standard of care in his treatment of this one patient?

* * *

A. Again, I don't know that -- I can't answer that "yes" or "no". My—my inclination is that to say he made an error because, does that fall outside of the standard of care, I'm not certain you could say that.

(Tr. at 121-122)

49. With respect to whether working 15-hour days for months would be likely to result in a higher level of errors, Dr. Peponis indicated that it would depend on the individual and their tolerance for such hours and whether they had adequate rest in between the days of work. (Tr. at 125)
Dr. Peponis agreed that it would be fair to say that a radiologist could handle a very heavy caseload, and perform within minimal standards, if this caseload were to persist only two or three days in a row. He stated that there are some “very adept” people who “can work in those situations with large numbers of hours, but those people have filtered, let’s say, to the top.” (Tr. at 124-126)
50. Dr. Peponis indicated that a radiologist can and will self-regulate his volume of work as needed. He stated his belief that, if a radiologist is not able to sustain the large number of hours that is required, he would change his practice or find another job. (Tr. at 126)
51. Dr. Peponis opined that working 56 hours per week, month in and month out, is “not that dissimilar from a lot of clinical practices through the city here, so I don’t know that if I – if that is my opinion, then there would be a lot of practitioners I work with that are in that threshold range.” (Tr. at 125)
52. Dr. Peponis stated that, in his group practice, his compensation is not based on the number of cases he reports. He is not paid “on a piece work basis,” However, he stated that the practice group is paid for all the work performed, so there is an incentive to be productive within the group, because one does not want to have “a bunch of partners that want to tend to do less.” (Tr. at 128-129)
53. Dr. Peponis testified that he typically works about nine hours per day, and about one weekend per month. He stated that he reads a full variety of ultrasound studies, vascular ultrasound studies, full-body CT scan, all sorts of MRIs, nuclear medicine studies, mammographies, and plain x-rays. He stated that, in his practice in hospitals and emergency rooms, an x-ray study usually involves one or two images, although an extremity articular radiograph may have three or four views. (Tr. at 98-102)
54. Dr. Peponis stated that he typically does about 20,000 cases per year or about 100 cases per day, but he has more complicated cases with more images, such as CT and MRI studies. On a routine day, 100 cases could involve eight to ten thousand images. Dr. Peponis testified that the average radiologist in his group has an annual volume of 20,000 to 30,000 cases per year, and that each has a different mixture of types of cases, varying from person to person. He explained that radiologists who do more complicated cases may do somewhat fewer cases. (Tr. at 104-106, 138, 139-142)
55. However, Dr. Peponis clarified that, with regard to reading CTs and MRIs, reading a thousand images of the same foot would be very different from reading a thousand images of different patients, and that it takes less time to review hundreds of images focusing on the same area. He explained that, with CT scanning and complex imaging, there is an ability to see the images sectioning through the anatomy, and, because of the ability to look at different planes through the anatomy, longitudinally or cross-sectionally, one can make a clinical decision more rapidly. (Tr. at 141-142)

56. Dr. Peponis explained that, if he looked at the x-ray film of Patient 1's foot as provided in State's Exhibit 4 and had to "hotlight" it, it would take him less than five minutes to review the film and complete the report. If he looked at Patient 1's x-ray study on the PACS, it would "probably be even quicker" because one can easily highlight, zoom, pan, and magnify. In contrast, if he looked at a CT scan of the foot, with 350 to 600 images, it would take him ten to fifteen minutes to consider the CT scan accurately and formulate a report. (Tr. at 143-144)
57. Dr. Peponis did not know of any guidelines or requirements regarding the maximum number of images that a radiologist could review per day. (Tr. at 107-108) When asked how radiologists would know when they "should cut off the number of images that they are reviewing in one day," he answered:

I don't know that there's a specific answer. Obviously if you're doing work or something in that realm, you know, like if you're too ill or too fatigued or couldn't work, obviously you'd want to stop.

At least in the clinical practice that I'm engaged in for the past 20-plus years, you know, is the general tendency to get the work done, so the workday pretty much depends on the work that is at hand. And on busier days you may have a longer day, and if you're fortunate, if you have a light day, you get done early, but it doesn't happen very often.

(Tr. at 107-108)

58. With regard to the reading of x-rays generally, Dr. Peponis described the high-resolution monitors used in the PAC system and the ability to enhance, invert, and magnify images. He explained that, when there are multiple views in one x-ray study, the user can choose to see all the views on the screen at the same time, in smaller size, or one can set the system at a higher level of magnification and then review all the images by "panning or pulling" the x-ray study to see all areas of all views. He explained that one could probably "tile out hundreds of images" on one screen if desired. The user has the option to set preferences. With regard to Patient 1's x-ray, Dr. Peponis would have had "each of those images" on a full-screen format. (Tr. at 101, 134-136)
59. Dr. Peponis also testified that his practice group has a quality-assessment program. He stated that the American College of Radiology has a rating system that distinguishes between different types of radiology errors, on a four-point scale based in part on patient harm or potential for patient harm. The first level of "variation or discrepancy" would be a "difference of opinion" that is not clinically significant. The second level is a variation of interpretation that is not clinically significant but might require additional investigation. The third and fourth levels are for errors that "may be" clinically significant and that "would be" clinically significant. (Tr. at 117-118)

By "clinically significant," Dr. Peponis means errors where there "might be or would be an adverse patient outcome." (Tr. at 117-118)

60. Dr. Peponis stated that, if the patient had the bullet fragment present for some time, then Dr. Lanese's error would not be a "significant" error on the scale he described. Dr. Peponis would rate the error regarding Patient 1's x-ray as a Category 2 error because there was no adverse outcome for the patient; that is, there was no "clinically detrimental finding in terms of patient outcome." (Tr. at 155-155; Tr. at 118-119)
61. Dr. Peponis testified that he has been personally acquainted with Dr. Lanese for about 15 years, that they see each other socially, and their families also interact socially. He stated that he had last seen Dr. Lanese socially a few months earlier, when the two of them had dinner. In addition, at one point they had explored forming a joint venture for their practice corporations. (Tr. at 131-133)
62. When asked how much he was being compensated for serving as an expert, Dr. Peponis replied, "I actually don't know." He stated that there had been no prearrangement regarding a fee. (Tr. at 133-134)

Dr. Lanese's Opinion Regarding the Care He Provided

63. Because Dr. Lanese did not provide a written report of expert opinion in advance of the hearing, he was not entitled to testify as an opinion witness at the hearing regarding the ultimate issue of minimal-standards violation. (Tr. at 199-200) However, he explained briefly why he had stated, during his deposition, that his radiological care of Patient 1 was not a departure from the minimal standard of care:

I looked at this as an incidental finding, and that the x-ray, itself, was read as negative for a fracture, and that, you now, I didn't record the fragments, but I think it was an incidental thing. As I say, in my past experience, bullet fragments in people are a common finding.

(Tr. at 201; St. Ex. 42-43)

Additional Testimony From Dr. Lanese Regarding His Medical Practice Generally

64. With regard to his high number of cases per annum, Dr. Lanese asserted at the hearing that his work consisted of cases that were "simple" or "very basic." He stated that he does not do the more sophisticated work such as CTs, MRIs, and sophisticated ultrasound tests. He explained that he typically sees x-ray studies of chest, skull, sinus, extremities, and abdomens. He explained that a chest is usually two views, that a skull is four views, and a foot is three views. (Tr. at 171-172, 176-177)
65. Dr. Lanese stated that the chest x-rays from nursing homes include a lot of one-image studies. He indicated that having only one image makes these studies easier to some extent, but he also noted that the x-rays from nursing homes are generally more difficult to read because the elderly patients have difficulty getting into position and in comprehending instructions to hold their breath. In contrast, the films he reads at the general-practice clinics are better films because the patients are younger and the x-ray technicians can talk to them. (Tr. at 174-175)

66. Dr. Lanese also indicated that chest x-rays from prisons are easier to do because the prisons take the x-rays specifically to rule out tuberculosis, and the films are of good quality. (Tr. at 175-176)
67. In addition, Dr. Lanese stated that prisoners' x-rays often involve traumatic injury from fighting. (Tr. at 175-176)
68. Dr. Lanese stated that the x-rays he received from Mobilex are transmitted digitally, and that he can read digital images more quickly than he can read images on film, such as the films he reviews at the clinics he visits. He explained that, with actual film, he may have to shuffle through envelopes and pieces of film, (Tr. at 173-174)
69. Dr. Lanese testified during his deposition that he has decreased the number of x-rays he is reading for Mobilex but is still working the same hours generally. (St. Ex. 6 at 27-28, 30-31)
70. At the hearing, Dr. Lanese stated that he had made changes in his practice since 2006. He stated that he had "decreased the volume of work" that he does. He stated that, in 2006, he worked "14, 15" hours per day, but, as of the hearing in September 2009, he was working "maybe eight" hours per day, and that he works only about one or two hours at home per day. He testified that he was reading about 2,000 cases per week in 2006 for Mobilex, but is now reading about 5,000 cases per month for Mobilex. (Tr. at 191-192)
71. Further, Dr. Lanese testified that he had been reading for 10 clinics in 2006 but was reading for only 5 clinics as of the time of the hearing.⁶ (Tr. at 194-195) He also testified that the number of clinics at the time of the hearing was only three or four. At one point, Dr. Lanese stated that his reason was that it had become "just too difficult to do it all." (Tr. at 169) At another point, however, he testified that there was no particular reason for cutting back "a little bit," as follows:

Q. Why has your work lessened? Any reason or reasons for that?

A. No. I've just decided to cut back a little bit.⁷

Q. Any other factors?

A. Not really.

(Tr. at 193-194)

The Performance Review System at Mobilex

72. Dr. Lanese testified that Mobilex had a quality-control program to review the radiologists' performance. Under this program, radiologists are routinely asked to review the reports of the other

⁶ In his deposition in 2007, Dr. Lanese testified that he worked for "six or eight" clinics. (St. Ex. 6 at 20-21)

⁷ The Hearing Examiner believes that cutting the number of cases at Mobilex from 2,000 per week to 5,000 per month is a drastic cut, almost in half. Similarly, cutting the number of clinics from 10 to 5 (or from 6-8 clinics in 2006 to 3-4 clinics currently) is a drastic cut in the number of cases handled for the clinics.

Mobilex radiologists. He presented the company's written policy called Continuous Quality Improvement and presented a copy of the worksheet for peer review. Dr. Lanese explained that, after he reviews a batch of other radiologists' reports, he makes comments and the office manager sends them to the main office in California. He stated that, if someone has a significant disagreement with one of his readings, he would be asked to read the image again. He testified that his contract allows for termination if the errors are unacceptable. (Tr. at 182-185)

73. Further, Dr. Lanese pointed to another quality-control mechanism for radiologists. He stated that, after his report is received, a nurse, physician assistant, or physician may see the conclusion that "there's nothing here," but will be concerned about "some serious clinical findings" they have, or they may have a copy of the x-ray to review, and they will ask the radiologist to read the x-ray again. Dr. Lanese stated that this type of request for re-reading happens in the "Midwest region" in about 100 cases per month. (Tr. at 187)

The Patient's Outcome

74. Barbara Volk, M.D., was the physician who ordered the x-ray for Patient 1 at the youth correctional institution. In September 2009, she provided a letter regarding her recollection of the incident, although she did not appear as a witness during the hearing to testify subject to cross-examination. She stated in her letter that, when the patient complained of foot pain, she was concerned about the potential for infection because there had been a gunshot injury to that foot previously. When Dr. Lanese's radiology report came in and included no mention of the metal fragments, she made a phone call, and Dr. Lanese amended his report. She stated: "The youth did not suffer any adverse consequences." (Resp. Ex. C)

Letters of Support for Dr. Lanese

75. Several physicians provided letters of support for Dr. Lanese, but did not appear as witnesses at hearing subject to cross-examination:
- Stephen Altic, D.O., who wrote among other things that Dr. Lanese provides "high quality and accurate radiologic interpretations" for patients in Dr. Altic's practice. (Resp. Ex. F)
 - Elliott Feldman, D.O., who wrote among other things that Dr. Lanese had visited his office on a weekly basis for 35 years to read x-rays and that Dr. Lanese's work was thorough and accurate. (Resp. Ex. G)
 - Charles May, D.O., who wrote among other things that Dr. Lanese has provided high quality and accurate radiologic interpretations for Dr. May's patients for more than 22 years. (Resp. Ex. H)
 - Charles Kistler, Jr., D.O., who wrote among other things that Dr. Lanese has provided radiology services to Dr. Kistler's patients on a weekly basis for more than 30 years, with accuracy "beyond reproach." Dr. Kistler stated that Dr. Lanese's "early detection of cancerous lesions, blockages and acute changes" had saved lives. (Resp. Ex. I)

CREDIBILITY DETERMINATIONS

The Hearing Examiner did not find Dr. Lanese to be a credible witness on several matters, such as the effect of his routinely long hours of work and high caseload, and his statement that there was no particular reason for his drastic reduction in caseload. This credibility determination was based on several factors. First, the Hearing Examiner observed Dr. Lanese at the hearing and assessed his demeanor and tone. Based on this assessment, the Hearing Examiner did not fully trust Dr. Lanese's testimony.

Second, the content of Dr. Lanese's testimony simply did not ring true in many instances, such as when he stated that he had no special reason for decreasing his workload by almost half. Third, Dr. Lanese provided information regarding Mobilex's quality-control program generally, while providing no data about the evaluation of his own work specifically. For example, he testified, and his expert commented upon, the Mobilex program for quality control, which apparently involves regular review of Dr. Lanese's readings by other radiologists. Dr. Lanese emphasized the details of the program, presenting Mobilex's written policy on quality assessment and accuracy review, the review key for radiologists, and a copy of the peer-review worksheet from Mobilex.⁸ The inference desired was that his work would have been reviewed on a regular basis and that he would not have maintained employment if there had been a significant problem with the accuracy of his work, and that the checks and balances provided by Mobilex would also serve to minimize any risk to patients in the future. However, the Hearing Examiner found that introducing substantial information about the quality-control program generally, while providing no specific data about assessment of Dr. Lanese's work, rendered the evidence unpersuasive overall and raised as many questions as it answered. For example, Dr. Lanese testified that his error rate was probably about 1%, but he provided nothing to document that testimony, and his testimony on this matter was found to lack reliability.

Indeed, Dr. Lanese provided no documentation of any kind to corroborate his testimony regarding the quantity of his work and the quality-assessment of his work. For example, he testified that he read 2,000 radiographic studies per week for Mobilex, but he provided no documentation from Mobilex or from his own records to corroborate his testimony. Given Dr. Lanese's testimony that he was paid by the piece, one would reasonably expect that Dr. Lanese and/or Mobilex would have compensation records regarding the number of cases he interpreted during the month in which he read Patient 1's x-rays. Further, it was noteworthy that the letter from Mobilex stated how many cases Dr. Lanese is *currently* reading per month, but was devoid of information regarding his level of reports in July 2006.⁹

The Mobilex letter of September 2009 was also deemed to have limited reliability and usefulness. The company, as Dr. Lanese's employer, had every reason to be protective. Moreover, the information in the letter is very general for the most part. With regard to the number of cases that

⁸The Hearing Examiner recognizes that certain evidence of physician peer-review may be protected from disclosure in certain circumstances. Here, however, it was Dr. Lanese who brought up the matter of peer review and offered evidence of Mobilex's policy on Quality Improvement and Radiologist Reading Accuracy, as well as the Mobilex's review key and worksheet.

⁹ The Hearing Examiner recognizes that the Board based its allegations on Dr. Lanese's own admissions in interrogatories and deposition testimony that he had handled about 2,000 cases per week. Thus, there was no requirement for Dr. Lanese to prove how many he actually read per week. However, his credibility was an issue in this case, and corroboration of his statements to the Board would have been persuasive with respect to his credibility in general.

Dr. Lanese handled for Mobilex, the company states that the volume of cases it sends to Dr. Lanese “has declined” over the “past few years.” Although Mobilex stated that Dr. Lanese *currently* receives about 5,500 cases per month, there is no indication of the number of cases that Dr. Lanese was handling before the caseload decreased, or at the time he committed the error regarding Patient 1.

ANALYSIS

1. *The Error in Reading the X-ray*

It is undisputed that Dr. Lanese made an error in reading the x-ray study of Patient 1’s foot. The question, then, is whether the error constitutes a “departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established” (which may be referred to herein as a “departure from minimal standards” or a “minimal-standards violation”). If it does, then the question is what type of discipline should be imposed.

Dr. Lanese argued at the hearing that his error did not constitute a departure from minimal standards, and he asks the Board to dismiss all charges in the Notice. Dr. Lanese asserted several points in his defense, including:

- a. His initial reading of the x-ray was accurate, and the “only” criticism of Dr. Lanese’s radiology report “was that it was incomplete.” (Tr. at 236)
- b. Dr. Lanese “self-corrected the mistake” within two weeks. (Tr. at 232)
- c. This x-ray was only one film of one patient during a long career. Several physicians in the community wrote letters stating that Dr. Lanese provided high-quality service as a radiologist for many years.
- d. There are checks and balances to protect patients from this type of error.
- e. The error was inconsequential; there was no patient harm.

Except for the first-listed item above, item (a), all the arguments above appear to have been presented “in mitigation.” In other words, these arguments are not relevant to whether a minimal-standards violation occurred but are relevant to the penalty phase, if any, when the Board determines the nature and extent of discipline that is appropriate.

To the extent that any of these arguments were presented to oppose a finding of a minimal-standards violation, the Hearing Examiner rejects them. First, with respect to the “accuracy” of the radiology report, the Hearing Examiner rejects the notion that an *omission* in a diagnostic reading is less serious than an affirmative act of stating something that is incorrect. The omission in this instance was not a borderline or debatable error. The foreign object is so patent in the lateral view that it is difficult to understand how a radiologist could miss it. Moreover, Dr. Lanese’s emphasis on hindsight, in which it became known that there was no adverse outcome, is misplaced. When he received the x-ray study to read, Dr. Lanese knew only that the patient had complained of pain in the foot. At that time, the presence of the metallic fragment was potentially significant.

Further, under Ohio law, in determinations of whether there was a departure from the minimal standards of care, the Board focuses on the acts, omissions and conduct of the physician, not on

whether there was harm to the patient. Under the Medical Practices Act, the lack of an adverse outcome for the patient is not relevant to whether a minimal-standards violation has occurred under R.C. 4731.22(B)(6). The extent of patient harm, if any, may be considered as a mitigating or aggravating factor when determining a sanction for a departure from the minimal standards of care. Indeed, during the hearing, one of Dr. Lanese's attorneys acknowledged that the lack of patient harm was relevant only as a mitigating factor. (Tr. at 72-73) The fact that radiologists may use a performance rating on which the seriousness of errors is based largely on patient outcome does not alter the standard to be applied under R.C. 4731.22(B)(6).

Second, Dr. Lanese did not "self correct" the mistake in his initial radiology report. He did not find the error by himself and report it independently. Instead, there was intervention by the referring physician, who had a problem with the reading and requested a second reading. Thus, another physician brought the issue to Dr. Lanese's attention, and only then did he reread the x-ray.

Third, if and when a minimal-standards violation occurs, the fact that the incident is the first and only minimal-standards violation in a long and otherwise unblemished career does not negate the violation that has occurred in this instance. Rather, the existence of multiple errors or the lack of any other errors constitutes an aggravating or mitigating factor for consideration when determining the appropriate sanction.

Fourth, Dr. Lanese argued that there are two quality-control mechanisms in his case that serve to reduce the likelihood of errors and avoid patient harm: (a) Mobilex has a quality-control program that helps reduce the rate of errors; and (b) when nurses and other healthcare professionals receive his radiology reports, they can compare his findings to their own viewing of the x-ray, and/or they can consider the patient's clinical symptoms and history, and if they have concerns about the reading, then they can ask for a re-read based on their concerns.

The Hearing Examiner agrees that the quality-control programs can and should help to maintain standards and reduce the rate of physician errors. The existence of such a program is not determinative, however, with respect to whether a minimal-standards violation occurred in this instance. It *does* have relevance to whether the problem identified in this matter is likely to result in less or more harm to the public, which relates to the appropriate sanction, if any.

The second quality-control argument made by Dr. Lanese is that primary caregivers (nurses, physician assistants, and physicians) can catch significant mistakes made by a radiologist and can request a "do over," thus avoiding potential harm to the patient. This argument is unpersuasive as to whether a minimal-standards violation has occurred. Of course, a good team of healthcare professionals functions interactively to prevent anyone's individual mistake from causing harm to the patient. Every member of an effective team strives to act as the safety net in case of errors, which may occur to some extent in any human endeavor. However, the fact that a nurse or other caregiver might detect a physician's error and take action to protect the patient does not negate the fact that the physician made an error that in and of itself—without regard to others who ought to notice it and help fix it—may constitute a departure from the physician's standard of care.

2. *The Allegations Regarding the Hours of Work and Volume of Cases Handled*

As explained more fully below, the Hearing Examiner did not find the evidence sufficient to conclude that the volume of cases and hours of work, *per se*, constituted a minimal-standards violation. That is, the evidence did not establish that the workload as alleged was too much for any radiologist in Ohio to work and that any radiologist who carries that workload is in violation of R.C. 4731.22(B)(6).

Nonetheless, the Hearing Examiner found the evidence convincing that the workload was too much for *Dr. Lanese* to handle without resulting in a departure from minimal standards in his reading of a patient's x-ray. In other words, the Hearing Examiner found that the unusually heavy workload over many months caused, or contributed to causing, the obvious error by *Dr. Lanese*, and that, accordingly, the Board would be within its discretion, when fashioning appropriate discipline, to impose limitations on this particular physician's workload.

In reaching this conclusion, the Hearing Examiner is cognizant that *Dr. Lanese*, in his closing argument, argued through counsel that there was "no testimony at all that correlates his work schedule, with hours that he works, number of cases he has, the type of x-rays he reads, with this mistake in not mentioning the fragment." (Tr. at 233) The Hearing Examiner disagrees. *Dr. Anderson*, the State's expert witness, testified that the "excessive" volume of cases was a probable factor in causing the error of omission on July 26, 2006. In the absence of any other explanation for the error, the Hearing Examiner agrees that it is more likely than not that the unusually high volume of cases together with the very high number of hours of work per week, over a long period of time, caused or contributed to causing the error here.

However, the Hearing Examiner cannot conclude, based on the quality and quantity of evidence at the hearing, that the number of cases and/or number of hours per week, in and of itself, constituted a departure from minimal standards of care, *per se*. The evidence at the hearing was not substantial or probative enough to demonstrate that any radiologist who reads 2,000 x-ray cases per week on average, involving 1 to 3 images in most cases, and who generally works about 56 hours per week, has violated the minimal standards based solely on the fact of that workload.

The Hearing Examiner found *Dr. Anderson* to be a knowledgeable and experienced radiologist, and found her to be an unbiased, credible witness. However, when asked if *Dr. Lanese's* workload constituted a minimal-standards violation, she did not immediately and unequivocally give a resounding "Yes." Instead, she answered: "My opinion is that the number of cases and the number of hours that *Dr. Lanese* admits that he works are more than normal, or more than what *most* radiologists would work." (Emphasis added)

At no point did *Dr. Anderson* make *Dr. Lanese's* workload sound appalling. To explain that "most" radiologists do not have nearly as heavy a workload as *Dr. Lanese* is a fairly tepid statement when one is determining compliance with minimal standards of care. It is not the same as saying that no radiologist can handle a workload like that and still conform to minimal standards of care, or that a radiologist with such a workload necessarily imperils patients. The Hearing Examiner acknowledges that, ultimately, *Dr. Anderson* did opine that the workload

itself constituted a departure from minimal standards and was “excessive.” However, when she explained her reasoning, it was not supported by a convincingly strong basis that the Hearing Examiner is convinced that Dr. Lanese, in essence, worked more than the maximum number of hours and cases that a radiologist in Ohio can work while conforming to minimal standards of care.

Moreover, Dr. Peponis, an equally knowledgeable and experienced radiologist, stated that Dr. Lanese’s number of hours, “while considerable, is not out of line with the number of work hours of many busy clinical radiologists.” He testified that the number of images “read by many practitioners may *exceed* the number of images” that Dr. Lanese reads. (Emphasis added)

When delineating a standard of care regarding the number of hours that a physician in Ohio may work in a week, or the number of cases that a physician may handle in a week, the Hearing Examiner is mindful that setting numeric standards must be considered carefully. Comparisons of one physician to another, and comparison of one practice to another, and determining the level of work that physicians may handle reasonably, is complicated by many factors, such as each individual’s health, age, stamina, experience, skill, and the exact nature of the work being performed. The workload that would be acceptable for one practitioner could be excessive for another. For example, the workload that would be acceptable for a healthy, well-rested, exceptionally skilled, 65-year-old practitioner could easily be excessive for a fatigued physician who is 45 years old and suffering from headaches. At the hearing, there was a lack of clear, strong and compelling evidence that, regardless of the individual practitioner, there is a level of cases or hours per week that is simply beyond what *any* radiologist reading x-rays can work without endangering patients.

Neither party presented medical literature regarding a maximum number of cases and/or hours that radiologists should not exceed. Overall, the evidence did not establish that a departure of minimal standards has been committed *solely* by virtue of reading 2,000 x-ray studies per week and/or working extremely long hours. However, the Board, with its collective medical expertise, does have the authority to rely on its own medical knowledge and experience in determining whether a minimal-standards violation was committed solely on the basis of the workload. The Board could rely on its own collective knowledge and experience to determine whether the alleged volume of cases and/or hours of work constituted a violation of minimal standards, in and of itself.

In sum, although the Hearing Examiner cannot conclude that Dr. Lanese’s workload constitutes a violation of minimal standards in and of itself, the evidence supports the conclusion that Dr. Lanese’s volume of cases and/or his hours of work created a significant risk of committing a violation of minimal standards, and that risk was realized when he provided medical care to Patient 1.

FINDINGS OF FACT

1. Donald D. Lanese, D.O., holds a certificate to practice medicine and surgery in Ohio. In the routine course of his medical practice, he reads and/or interprets radiographs, also known as x-rays. On July 26, 2006, Dr. Lanese read and/or interpreted a radiograph with three views on one film showing the foot of Patient 1, a 17-year-old incarcerated youth. Patient 1 is identified on a Patient Key that is not subject to public disclosure.

In his report dated July 26, 2006, Dr. Lanese reported that there was “No acute bony or joint abnormality.” He did not mention the presence of a metallic fragment in the soft tissue of the left foot.

On August 9, 2006, Dr. Lanese reread the same radiograph of Patient 1’s foot, and he reported his impression as follows: “There is a bullet fragment noted adjacent to the anterior superior border of the calcaneus.”

2. Dr. Lanese has admitted that he had made an error in reading the radiograph of Patient 1.
3. Prior to the hearing, Dr. Lanese admitted that he routinely handled about 2,000 cases per week in 2006 for Mobilex alone. His testimony at the hearing related to 2,000 cases per week in general.

Prior to the hearing, Dr. Lanese acknowledged during his deposition that he had worked twelve to thirteen hours a day, four days per week, and an additional four hours on the weekend. During the hearing, Dr. Lanese testified that he generally worked fourteen to fifteen hours per day in 2006, which was consistent with the statement in his interrogatory answers; during the hearing, he was not asked about shorter hours on weekends.

Prior to the hearing, Dr. Lanese testified in his deposition that he typically would read approximately 30 radiographs each hour; he also estimated, however, that he would spend about two to three minutes reading each radiograph.

The Hearing Examiner finds that Dr. Lanese routinely handled at least 2,000 cases per week in 2006. The Hearing Examiner further finds that Dr. Lanese worked 14 to 15 hours per day, four days per week, and worked about four hours during the weekends.

CONCLUSIONS OF LAW

1. The acts, conduct, and/or omissions of Donald D. Lanese, D.O., as set forth above in Findings of Fact 1 and 2, constitute a “departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that language is used in R.C. 4731.22(B)(6).

2. The evidence is insufficient to establish that Dr. Lanese's acts, omissions and/or conduct as set forth above in Finding of Fact 3, constitute a "departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that language is used in R.C. 4731.22(B)(6).

However, the evidence is sufficient to establish that Dr. Lanese's acts, omissions and/or conduct, as set forth above in Finding of Fact 3, individually and/or collectively, constituted a contributing factor in causing the failure to conform to minimal standards as set forth above in Conclusion of Law 1, and provide sufficient support for limiting Dr. Lanese's hours of work and/or his volume of cases as a radiologist.

Discussion of Proposed Order

Although the Hearing Examiner rejected Dr. Lanese's arguments with respect to whether a minimal-standards violation had been established, the Hearing Examiner accepts many of those arguments on the issue of mitigation. Only one medical error was proven, and there is no evidence of patient harm. Further, Dr. Lanese has already taken voluntary action to limit his volume of cases and hours of work. The Hearing Examiner sees no need for a suspension of his certificate to practice. Likewise, the error does not appear to have been resulted from lack of knowledge, so there is no proposal for educational courses. Nonetheless, the State did establish a departure from minimal standards with regard to Patient 1 *and* that Dr. Lanese's hours of work and volume of cases as worked in 2006 were likely a contributing factor in causing the minimal-standard violation. Accordingly, a permanent limitation on Dr. Lanese's volume of cases is proposed, with monitoring and reporting during a two-year probationary period.

The proposed limitation is based on Dr. Anderson's persuasive testimony that reading 200 x-rays per day on the PAC System would be "pushing it" for her. Thus, a workload involving no more than 1,100 x-ray cases per week is proposed, which would allow an average to above-average workload.¹⁰ This limitation on volume of cases would not apply solely to the Mobilex employment but would apply to all cases handled for all patients.

¹⁰This limitation would allow various configurations. For example, Dr. Lanese could work five days of reading 200 cases per day, and an additional day of reading 100 cases, or he could work only four days per week and do more cases per day. On a monthly basis, reading 1,100 cases per week translates to about 4,766 per month.

PROPOSED ORDER

It is hereby **ORDERED** that:

- A. **PROBATION:** The certificate of Donald D. Lanese, D.O., to practice osteopathic medicine and surgery in the State of Ohio shall be subject to the following PROBATIONARY terms, conditions, and limitations for a period of at least two years:
1. **Obey the Law:** Dr. Lanese shall obey all federal, state, and local laws, and all rules governing the practice of medicine and surgery in Ohio.
 2. **Practice Limitation:** Dr. Lanese is limited to, and shall not handle or perform more than, 1,100 x-ray cases per week.
 3. **Declarations of Compliance:** Dr. Lanese shall submit quarterly declarations under penalty of Board disciplinary action and/or criminal prosecution, stating whether there has been compliance with all the conditions of this Order. The first declaration must be received in the Board's offices on or before the first day of the third month following the month in which this Order becomes effective. Subsequent declarations must be received in the Board's offices on or before the first day of every third month.
 4. **Personal Appearances:** Dr. Lanese shall appear in person for an interview before the full Board or its designated representative during the third month following the month in which this Order becomes effective, or as otherwise directed by the Board. Subsequent personal appearances shall occur every six months thereafter, and/or as otherwise directed by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.
 5. **Monitoring Physician:** Within 30 days of the effective date of this Order or as otherwise determined by the Board, Dr. Lanese shall submit the name and curriculum vitae of a monitoring physician for prior written approval by the Secretary and Supervising Member of the Board. In approving an individual to serve in this capacity, the Secretary and Supervising Member will give preference to a physician who practices in the same locale as Dr. Lanese and who is engaged in the same or similar practice specialty.

The monitoring physician shall monitor Dr. Lanese and his medical practice, and shall review Dr. Lanese's radiology reports and/or patient charts. The review may be done on a random basis, with the frequency and number of cases reviewed to be determined by the Board.

Further, the monitoring physician shall provide the Board with reports on the monitoring of Dr. Lanese and his medical practice, and on the review of Dr. Lanese's radiology reports and/or patient charts. The monitoring reports shall include the number

of cases handled/performed by Dr. Lanese during the reporting period. Dr. Lanese shall ensure that the monitoring reports are forwarded to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Lanese's declarations of compliance.

In the event that the designated monitoring physician becomes unable or unwilling to serve in this capacity, Dr. Lanese shall immediately so notify the Board in writing. In addition, Dr. Lanese shall make arrangements acceptable to the Board for another monitoring physician within 30 days after the previously designated monitoring physician becomes unable or unwilling to serve, unless otherwise determined by the Board. Dr. Lanese shall further ensure that the previously designated monitoring physician also notifies the Board directly of his or her inability to continue to serve and the reasons therefor.

The Board, in its sole discretion, may disapprove any physician proposed to serve as Dr. Lanese's monitoring physician, or may withdraw its approval of any physician previously approved to serve as Dr. Lanese's monitoring physician, in the event that the Secretary and Supervising Member of the Board determine that any such monitoring physician has demonstrated a lack of cooperation in providing information to the Board or for any other reason.

6. **Submit Records**: Dr. Lanese shall submit to the Board a written statement of his weekly volume of work, including all work performed as an employee or contractor. Dr. Lanese shall further submit copies of all billing records and all other records regarding compensation for work as a physician or that reliably show the volume of cases he handled to the Board's satisfaction. Dr. Lanese shall certify that all such documents are complete and accurate. Dr. Lanese shall ensure that the documents are forwarded to the Board on a quarterly basis and are received in the Board's offices no later than the due date for Dr. Lanese's declarations of compliance.
- B. **TERMINATION OF PROBATION; PERMANENT LIMITATION**: Upon successful completion of probation, as evidenced by a written release from the Board, Dr. Lanese's certificate will be restored, but shall thereafter be permanently LIMITED and RESTRICTED as specified in Paragraph A(2) above.
- C. **REQUIRED REPORTING WITHIN 30 DAYS OF THE EFFECTIVE DATE OF THIS ORDER**:
1. **Required Reporting to Employers and Others**: Within 30 days of the effective date of this Order, Dr. Lanese shall provide a copy of this Order to all employers or entities with which he is under contract to provide healthcare services (including but not limited to third-party payors), or is receiving training; and the chief of staff at each hospital or healthcare center where he has privileges or appointments.

Further, Dr. Lanese shall promptly provide a copy of this Order to all employers or entities with which he contracts in the future to provide healthcare services (including but not limited to third-party payors), or applies for or receives training, and the chief of staff at each hospital or healthcare center where he applies for or obtains privileges or appointments. This requirement shall continue until Dr. Lanese receives from the Board written notification of the successful completion of probation.

In the event that Dr. Lanese provides any healthcare services or healthcare direction or medical oversight to any emergency medical services organization or emergency medical services provider in Ohio, within 30 days of the effective date of this Order, he shall provide a copy of this Order to the Ohio Department of Public Safety, Division of Emergency Medical Services. This requirement shall continue until Dr. Lanese receives from the Board written notification of the successful completion of his probation.

2. **Required Reporting to Other State Licensing Authorities:** Within 30 days of the effective date of this Order, Dr. Lanese shall provide a copy of this Order to the proper licensing authority of any state or jurisdiction in which he currently holds any professional license, as well as any federal agency or entity, including but not limited to the Drug Enforcement Agency, through which he currently holds any license or certificate. Also, Dr. Lanese shall provide a copy of this Order at the time of application to the proper licensing authority of any state in which he applies for any professional license or reinstatement/restoration of any professional license. This requirement shall continue until Dr. Lanese receives from the Board written notification of the successful completion of his probation.
3. **Required Documentation of the Reporting Required by Paragraph C:** Dr. Lanese shall provide this Board with **one** of the following documents as proof of each required notification within 30 days of the date of each such notification: (1) the return receipt of certified mail within 30 days of receiving that return receipt, (2) an acknowledgement of delivery bearing the original ink signature of the person to whom a copy of the Order was hand delivered, (3) the original facsimile-generated report confirming successful transmission of a copy of the Order to the person or entity to whom a copy of the Order was faxed, or (4) an original computer-generated printout of electronic mail communication documenting the e-mail transmission of a copy of the Order to the person or entity to whom a copy of the Order was e-mailed.

EFFECTIVE DATE: This Order shall become effective immediately upon the mailing of the notification of approval by the Board.



Patricia A. Davidson
Hearing Examiner

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

EXCERPT FROM THE DRAFT MINUTES OF JANUARY 13, 2010

REPORTS AND RECOMMENDATIONS AND PROPOSED FINDINGS AND PROPOSED ORDERS

Dr. Amato announced that the Board would now consider the Reports and Recommendations, and the Proposed Findings and Proposed Order appearing on its agenda.

Dr. Amato asked whether each member of the Board had received, read and considered the hearing records; the Findings of Fact, Conclusions of Law and Proposed Orders, and any objections filed in the matters of: Cherry Lynn Hively, M.T.; William Balint Kerek, M.D.; Donald D. Lanese, D.O.; Wayne Marshall Williams, M.D.; and Megan Marie Xenakis; and the Proposed Findings and Proposed Order in the matter of Nancy Jayne Lisch, M.D. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Talmage	- aye
	Dr. Suppan	- aye
	Dr. Varyani	- aye
	Mr. Ogg	- aye
	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Amato	- aye
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- aye
	Dr. Madia	- aye

Dr. Amato asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

ROLL CALL:	Mr. Albert	- aye
	Dr. Talmage	- aye
	Dr. Suppan	- aye
	Dr. Varyani	- aye
	Mr. Ogg	- aye
	Dr. Strafford	- aye
	Mr. Hairston	- aye

Dr. Amato - aye
Dr. Stephens - aye
Dr. Mahajan - aye
Dr. Steinbergh - aye
Dr. Madia - aye

Dr. Amato noted that, in accordance with the provision in Section 4731.22(F)(2), Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further participation in the adjudication of these matters. In the matters before the Board today, Dr. Talmage served as Secretary and Mr. Albert served as Supervising Member.;

Dr. Amato reminded all parties that no oral motions may be made during these proceedings.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

.....

Dr. Talmage was not present when the discussion of this case began.

.....

DONALD D. LANESE, D.O.

Dr. Amato directed the Board's attention to the matter of Donald D. Lanese, D.O. He advised that objections were filed to Hearing Examiner Davidson's Report and Recommendation and were previously distributed to Board members.

Dr. Amato continued that a request to address the Board has been timely filed on behalf of Dr. Lanese. Five minutes would be allowed for that address. Dr. Steinbergh stated that she will abstain from the discussion and vote on Dr. Lanese's case.

Dr. Lanese was accompanied by his attorneys, Elizabeth Y. Collis, Esq., and Gerald Sunbury, Esq. Ms. Collis stated that she filed objections to the Report and Recommendation.

Dr. Lanese thanked the Board for giving him the opportunity to appear before the Board. Dr. Lanese stated that he had been a practicing radiologist for more than forty years and was licensed to practice medicine in thirteen other states besides Ohio. Dr. Lanese stated that his current practice involves reading only x-rays, not MRIs, CT scans, or mammograms; Dr. Lanese uses a computer to read digital x-ray images from facilities such as nursing homes and prisons. Dr. Lanese reads images in this fashion from his home, as well as from his office in Worthington, Ohio.

Dr. Lanese stated that he had never had an issue before the State Medical Board of Ohio or any other state

board. Dr. Lanese stated that the issue before the Board involved one x-ray which he read and provided to a patient three and one-half years ago. Dr. Lanese admitted that on his first read, he failed to note a bullet fragment in the patient's foot. The patient's physician sent the image back to Dr. Lanese for a second read, whereupon Dr. Lanese added an addendum which reported that metal fragments were present. Dr. Lanese stated that no harm came to the patient and the patient's physician did not change the treatment following Dr. Lanese's second reading.

Dr. Lanese stated that his correction of the initial reading of the x-ray indicated that the check and balance system utilized by his practice works. Dr. Lanese stated that, in this case, the x-ray was re-read at the request of the treating health professional. In addition to re-reading upon request, Dr. Lanese described his practice's check and balance system, wherein on a weekly basis another radiologist out of the twenty-six radiologists in Dr. Lanese's practice reviews x-rays and x-ray reports, then notes any disagreements.

Dr. Lanese predicted that if the Board imposed probation or otherwise limited his license, such action would initiate a domino effect and lead to investigations and possible discipline from other medical boards in states where he holds a license. Dr. Lanese stated that such a process would be financially devastating. Dr. Lanese respectfully requested that the Board to dismiss the case against him or to take no further action.

Mr. Sunbury also spoke for Dr. Lanese. Mr. Sunbury reiterated that the case against Dr. Lanese involved one x-ray read three and one-half years ago, and no harm came to the patient. Mr. Sunbury stated that Dr. Lanese's initial reading of the x-ray was an incomplete reading, not an inaccurate reading. Mr. Sunbury stated that he had reviewed the public documents of prior Board meetings and found no cases similar to Dr. Lanese's case. Mr. Sunbury emphasized Dr. Lanese's assertion that an action against his Ohio medical license would result in actions from other state medical boards and that this would be catastrophic.

Mr. Sunbury stated that Dr. Lanese reads x-rays from over one thousand institutions, including nursing homes. Mr. Sunbury further stated that Dr. Lanese was an independent contractor for a large corporation. Mr. Sunbury opined that the supervision suggested by the Report and Recommendation was unnecessary and would result in Dr. Lanese losing his job. Mr. Sunbury repeated Dr. Lanese's request that the case be dismissed or no further action be taken.

Dr. Amato asked whether the Assistant Attorney General wished to respond. Ms. Pfeiffer stated that she did.

Ms. Pfeiffer stated that in Dr. Lanese's objections, he made reference to his expert witness, who testified at hearing. Dr. Lanese's objection asserted that the expert had opined that the failure to note the bullet fragments did not fall below the minimal standards of care. Ms. Pfeiffer stated that this was incorrect and noted that Dr. Lanese's expert was, at best, ambiguous in responding to that question.

Ms. Pfeiffer stated that when asked at the hearing if Dr. Lanese's failure to note the metallic fragment in the first report fell below the minimum standards of care, Dr. Lanese's expert responded, "I can't say that is

necessarily the case. I can't say 'yes' and I can't say 'no.'" The expert was further questioned, "Do you believe that Dr. Lanese deviated from the standard of care in his treatment of this one patient?" The expert answered, "Again, I don't know that. I can't answer that 'yes' or 'no.' My inclination is to say that he made an error because...does that fall outside the standard of care? I'm not certain." In contrast, Ms. Pfeiffer observed that the Board's expert was very clear that the failure to note the metallic fragments in that particular x-ray was a departure from and a failure to conform to the minimal standards of care.

Ms. Pfeiffer provided the x-ray film in question for the Board, stating that she brought it for the benefit of the non-physician members of the Board. Ms. Pfeiffer stated that, although she herself was not a physician, she could clearly see the metallic fragments and suggested that the non-physician members of the Board should be able to see it as well.

Regarding Dr. Lanese's system of checks and balances, Ms. Pfeiffer pointed out that the second reading was requested by the physician at the prison facility where Patient 1 was incarcerated, and the second reading did not result from Dr. Lanese's internal office procedures.

Ms. Pfeiffer stated that the Hearing Examiner found that Dr. Lanese handled about 2,000 cases per week, worked fourteen to fifteen hours a day, at least four days a week, and up to four hours on the weekend. Ms. Pfeiffer stated that the Board's expert witness concluded that Dr. Lanese's work volume must have at least contributed to the error in this case. Ms. Pfeiffer agreed with the expert witness and stated that Dr. Lanese failed to identify the metallic fragments because he worked too fast and was reading too much. Ms. Pfeiffer opined that it was appropriate for the Board to consider the volume of Dr. Lanese's work and to make limitations on his license to ensure that an error of this nature did not occur in the future.

DR. VARYANI MOVED TO APPROVE AND CONFIRM MS. DAVIDSON'S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND PROPOSED ORDER IN THE MATTER OF DONALD D. LANESE, D.O. DR. MADIA SECONDED THE MOTION.

Dr. Amato stated that he would now entertain further discussion in the above matter.

Dr. Madia stated that the metallic fragments were very obvious on the x-ray film. Dr. Madia opined that the error was not a result of a lack of knowledge, noting that even non-physicians could identify the bullet fragments. Dr. Madia opined that the error must have resulted from Dr. Lanese's large workload.

Dr. Madia noted that, according to Dr. Lanese's testimony, he read about 100,000 films per year. At one point, Dr. Lanese claimed that he made errors on four to ten films per year. However, Dr. Lanese later stated that his error rate was "probably 1%." Dr. Madia pointed out that 1% of 100,000 was 1,000, indicating that Dr. Lanese made 1,000 error per year. Dr. Madia was uncertain which figure was more correct.

Dr. Madia further noted that Dr. Lanese's company wrote a letter stating that, while they had a quality assurance program, the procedures to ensure quality were not clearly defined.

Dr. Madia stated that Dr. Lanese worked fifteen hours per day, five days per week. Dr. Madia further stated that, according to Dr. Lanese's testimony, Dr. Lanese saw thirty-three films per hour, or approximately 2 minutes per film. Dr. Madia pointed out that at that rate, Dr. Lanese would have to read films non-stop for fifteen hours a day, with no coffee break, no lunch break, and no bathroom break, to account for his volume. Dr. Madia opined that this was impossible. Dr. Madia also noted that Dr. Lanese's compensation was based on the number of films he read.

Dr. Madia stated that, in the opinion of the state's witness, 150-200 films per day was the approximate limit which a radiologist could read without compromising quality; Dr. Lanese read 400-500 films per day. Also, Dr. Madia stated that, according to Dr. Lanese's expert witness, Dr. Lanese also compared the x-ray images with MRIs and CT scans. Dr. Madia pointed out that a CT scan could include 450 images.

Dr. Madia noted that the Proposed Order would limit the number of films Dr. Lanese could read to 1,100 per week and provided for a physician to monitor Dr. Lanese's quality. Although Dr. Madia felt the 1,100 films per week was still too many, he agreed with the Proposed Order.

Dr. Stephens stated that she disagreed with the proposed order and opined that the case against Dr. Lanese should be dismissed or no action taken. Dr. Stephens stated that, as an orthopedic surgeon, she routinely saw x-rays in which a radiologist had missed something. Dr. Stephens stated that practitioners of every profession made mistakes.

Referring to the x-ray film in question, Dr. Stephens agreed that the metallic fragments were readily visible on the lateral view. However, Dr. Stephens stated that she could see how the fragments could be missed on the oblique view, where the fragments were on the side of the film and out of focus.

Dr. Stephens further stated that she had no concerns about Dr. Lanese's volume of work. Dr. Stephens stated that some people can read films faster than others and that some people wanted to work fifteen hours per day. Dr. Stephens opined that it was not the place of the Board to tell someone how much work they could perform.

Dr. Stephens noted that the treating physician ordered the x-ray to rule out a fracture. Dr. Stephens stated that if one is asked to rule out a fracture, the physician may focus on that and not notice other diagnoses. Dr. Stephens stated that Dr. Lanese correctly ruled out a fracture on his initial reading.

Dr. Stephens reiterated her opinion that this case should be dismissed.

Dr. Suppan agreed with Dr. Stephens. Dr. Suppan stated that based on her experience as a podiatrist who has read foot x-rays for over twenty-five years, she considered this to be simply an error. In her practice, Dr. Suppan also saw things on films which had been missed by a radiologist and speculated that other physicians may have seen things that she had missed.

Dr. Suppan stated that in her current position as a hospital administrator, she knew that medical errors occurred on a daily basis, necessitating failsafe systems to evaluate those errors and prevent them from happening. Dr. Suppan saw no malice or intent in this case and did not see this as a minimal standards issue. Dr. Suppan noted that she was not a radiologist, and therefore did not opine on the appropriateness of Dr. Lanese's volume of work. However, Dr. Suppan considered this incident to be a simple error.

Dr. Madia agreed that every physician will miss something on occasion. However, Dr. Madia expressed concern about the volume of Dr. Lanese's workload. Dr. Stephens stated that some people are able to work at that level. Dr. Madia stated that with an error rate of 1%, Dr. Lanese would make 1,000 errors per year. Dr. Suppan stated that no physician, including the physicians on the Board, can say that they have never made an error.

Dr. Varyani stated that he understood that every company that employs radiologists measures the radiologists' error rate, or the incidences in which the radiologist's diagnosis is different from the initial diagnosis. Dr. Varyani stated that if Dr. Lanese's error rate was within an acceptable range in relation to other radiologists, then Dr. Varyani would be inclined to support dismissing the case.

Ms. Pfeiffer addressed the Board and pointed out that among the options available to the Board were Dismissal and No Further Action. Ms. Pfeiffer explained that Dismissal would indicate that the Board found no violation of the law. Ms. Pfeiffer continued that No Further Action would indicate that the Board found that a violation occurred, but declined to impose any disciplinary action.

DR. STEPHENS MOVED TO AMEND THE PROPOSED ORDER IN THE MATTER OF DONALD D. LANESE, D.O. TO REFLECT DISMISSAL OF THE CASE. DR. SUPPAN SECONDED THE MOTION.

Mr. Ogg noted that a general practitioner would be expected to spend approximately fifteen minutes with a patient and asked why a radiologist would be expected to spend less time reviewing a patient's x-ray films. Dr. Mahajan stated that examining a patient and reviewing a patient's x-ray films were not comparable actions. Dr. Stephens agreed. Mr. Ogg stated that examining a patient and reviewing x-ray films, although different, were both medical procedures. Dr. Amato explained that examining a patient is more extensive than reviewing an x-ray film. Dr. Varyani agreed that the complexity of the two procedures were completely different.

Dr. Varyani stated that Dr. Lanese certainly erred by failing to identify the bullet fragments, but was not certain if this constituted a violation of the minimal standards of care. Dr. Varyani stated that he was willing to support dismissing the case.

Dr. Amato was uncertain if Dismissal was appropriate in this case. Dr. Amato stated that Dismissal meant that no violation occurred. Dr. Amato opined that failing to identify the bullet fragment was below the minimal standards of care and felt the No Further Action would be more appropriate.

Dr. Stephens opined that the case against Dr. Lanese should not be before the Board. Dr. Stephens stated that a ruling of No Further Action would indicate that Dr. Lanese did something wrong, whereas Dr. Stephens opined that Dr. Lanese did not do anything wrong. Dr. Stephens stated that Dr. Lanese was asked to rule out a fracture, and he correctly did that. Dr. Stephens stated that no harm came to the patient and argued that Dismissal was the proper course of action. Dr. Varyani argued that Dr. Lanese did do something wrong, but agreed with Dr. Stephens that Dismissal was appropriate.

Mr. Albert left the meeting during the previous discussion.

A vote was taken on Dr. Stephens' motion to amend:

ROLL CALL:	Dr. Varyani	- aye
	Dr. Suppan	- aye
	Mr. Ogg	- nay
	Dr. Strafford	- aye
	Mr. Hariston	- nay
	Dr. Madia	- nay
	Dr. Stephens	- aye
	Dr. Mahajan	- abstain
	Dr. Steinbergh	- abstain
	Dr. Amato	- nay

The motion did not carry.

DR. MAHAJAN MOVED TO AMEND THE PROPOSED ORDER IN THE MATTER OF DONALD D. LANESE, D.O., TO REFLECT NO FURTHER ACTION. MR. HAIRSTON AGREED.

A vote was taken on Dr. Mahajan's motion to amend:

ROLL CALL:	Dr. Varyani	- aye
	Dr. Suppan	- aye
	Mr. Ogg	- aye
	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Madia	- nay
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- abstain
	Dr. Amato	- aye

The motion carried.

DR. VARYANI MOVED TO APPROVE AND CONFIRM MS. DAVIDSON'S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND PROPOSED ORDER, AS AMENDED, IN THE MATTER OF DONALD D. LANESE, D.O. DR. MAHAJAN SECONDED THE MOTION. A vote was taken:

ROLL CALL:	Dr. Varyani	- aye
	Dr. Suppan	- aye
	Mr. Ogg	- aye
	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Madia	- aye
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- abstain
	Dr. Amato	- aye

The motion carried.

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127



Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

March 11, 2009

Case number: 09-CRF- 031

Donald D. Lanese, D.O.
155 West Main Street, #1904
Columbus, Ohio 43215

Dear Doctor Lanese:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio [Board] intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice osteopathic medicine and surgery, or to reprimand you or place you on probation for one or more of the following reasons:

- (1) In the routine course of your medical practice, you read and/or interpret radiographs. On or about July 26, 2006, you read and/or interpreted a radiograph with three views on one film of the foot of Patient 1, a 17 year old incarcerated youth. Patient 1 is identified on the attached Patient Key. (The Patient Key is confidential and not subject to public disclosure). In your report prepared on or about the same day, you reported your impression as "No acute bony or joint abnormality." You did not note or mention the presence of metallic fragments in the soft tissues of the lateral foot.

On or about August 9, 2006, you reread the same radiograph of Patient 1's foot. On or about that same date, you reported your impression as "There is a bullet fragment noted adjacent to the anterior superior border of the calcaneus."

- (2) On or about February 12, 2008, you admitted that initially you did not correctly interpret the radiograph. You also admitted that you handle about 2,000 cases a week, working twelve to thirteen hours a day, four to five days a week. You also admitted that you read approximately 30 radiographs each hour and that you spend two to three minutes reading each radiograph.

Your acts, conduct, and/or omissions as alleged in paragraphs (1) and (2) above, individually and/or collectively, constitute "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar

Mailed 3-12-09

circumstances, whether or not actual injury to a patient is established," as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty days of the time of mailing of this notice.

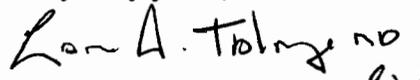
You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice osteopathic medicine and surgery or to reprimand you or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, provides that "[w]hen the board refuses to grant a certificate to an applicant, revokes an individual's certificate to practice, refuses to register an applicant, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate."

Copies of the applicable sections are enclosed for your information.

Very truly yours,


Lance A. Talmage, M.D. *no*
Secretary *W*

LAT/CDP/flb
Enclosures

CERTIFIED MAIL #91 7108 2133 3936 3066 6672
RETURN RECEIPT REQUESTED

**IN THE MATTER OF
DONALD D. LANESE, D.O.**

09-CRF-031

**MARCH 11, 2009 NOTICE OF
OPPORTUNITY FOR HEARING
PATIENT KEY**

**SEALED TO
PROTECT PATIENT
CONFIDENTIALITY AND
MAINTAINED IN CASE
RECORD FILE.**