BEFORE THE BOARD IOWA BOARD OF MEDICINE

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IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST

SALAHUDDIN SYED, M.D., RESPONDENT

FILE No. 02-14-406

****

TERMINATION ORDER

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Date: June 30, 2017.

1. **Iowa Medical License:** Respondent was issued Iowa medical license MD-37105 on March 12, 2007. Respondent's Iowa medical license is active and will next expire on March 1, 2018.

2. **Jurisdiction:** The Board has jurisdiction in this matter pursuant to Iowa Code chapters 147, 148 and 272C.

3. **Practice Setting:** Respondent is an Iowa-licensed physician who practices anatomic and clinical pathology in Marshalltown, Iowa.

4. **Statement of Charges:** On July 10, 2015, the Board filed a Statement of Charges against Respondent alleging he demonstrated professional incompetency and/or practice harmful or detrimental to the public in violation the laws and rules governing the practice of medicine in Iowa when he failed to provide appropriate pathology services to multiple patients in Marshalltown, Iowa.

5. **Findings of Fact, Conclusions of Law, Decision and Order:** The Board held a hearing on January 21 and 22, 2016, and issued a Findings of Fact, Conclusions of Law, Decision and Order on April 8, 2016. The Board concluded that Respondent demonstrated professional incompetency and practice harmful or detrimental to the public when he misdiagnosed a well-differentiated squamous cell carcinoma in vulvar tissue as a keratoacanthoma in a single patient and when he failed to seek consultations in cases of suspected melanoma. The Board issued Respondent a Citation and Warning for engaging in professional incompetency and practice harmful and detrimental to the public. The Board ordered Respondent to arrange for continuing audits of 5% of his cases by an outside pathology laboratory approved by the Board and ensure that the auditing entity submits a report to the Board on a quarterly basis. The Board also ordered Respondent to obtain consultation with a Board-approved, board-certified, dermatopathologist prior to issuing any pathology report for any cases of suspected melanoma. Finally, the Board ordered Respondent to submit a professional paper discussing the diagnostic criteria for well-differentiated squamous cell carcinoma and keratoacanthoma in vulvar tissue to the Board for approval.

6. **Request for Termination of the April 8, 2016, Findings of Fact, Conclusions of Law, Decision and Order:** Recently, Respondent submitted a request to terminate the terms of the April 8, 2016, Findings of Fact, Conclusions of Law, Decision and Order. Respondent demonstrated that he has fully complied with the terms of the April 8, 2016, Order, and that he has an employment opportunity at a large pathology group practice that will provide a greater opportunity for professional collaboration and safeguards for his pathology practice in the future.

7. **Termination of the April 8, 2016, Findings of Fact, Conclusions of Law, Decision and Order:** On June 30, 2017, the Board voted to terminate the terms of the April 8, 2016, Findings of Fact, Conclusions of Law, Decision and Order. The Board noted that Respondent:

A. Submitted a professional paper discussing the diagnostic criteria for well-differentiated squamous cell carcinoma and keratoacanthoma in vulvar tissue to the Board for approval.

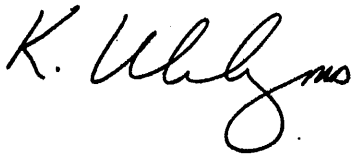
B. Successfully completed continuing audits of 5% of his cases by an outside pathology laboratory approved by the Board and ensured that the auditing entity submitted a report to the Board on a quarterly basis.

C. Obtained consultation with a Board-approved, board-certified, dermatopathologist prior to issuing any pathology report for any cases of suspected melanoma.

D. Has an employment opportunity at a large pathology group practice that will provide a greater opportunity for professional collaboration and safeguards for his pathology practice in the future.

THEREFORE IT IS HEREBY ORDERED: that the terms of the April 8, 2016, Findings of Fact, Conclusions of Law, Decision and Order are terminated and Respondent's Iowa medical license is returned to its full privileges, free and clear of all restrictions.

This Order is issued by the Board on June 30, 2017.



Kyle G. Ulveling, M.D., Chairperson
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BEFORE THE IOWA BOARD OF MEDICINE

IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST:	)	DIA NO. 15IMB005 FILE NO. 02-14-406
SALAHUDDIN SYED, M.D.,	)	FINDINGS OF FACT, CONCLUSIONS OF LAW,
Respondent	)	DECISION AND ORDER

Date: April 8, 2016.

On July 10, 2015, the Iowa Board of Medicine (Board) found probable cause to file a Statement of Charges against Salahuddin Syed, M.D. (Respondent) charging him with professional incompetency and engaging in practice harmful or detrimental to the public. The Statement of Matters Asserted specified that the charges relate to Respondent's actions in multiple cases.[1] A hearing was originally scheduled for September 10, 2015, but was twice continued.

The hearing was held on January 21 and 22, 2016, before the following quorum of the Board: Kyle Ulveling, M.D, Acting Chairperson, Carole Frier, D.O., and Julie Carmody, M.D., physician members and Diane Clark, Mary Jo Romanco, and Paul Thurlow, public members. Respondent was represented by attorney Connie Diekema. Assistant Attorney General Julie Bussanmas represented the State. The hearing was closed to the public, pursuant to Iowa Code section 272C.6(l) and 653 IAC 25.18(12). The hearing was recorded by a certified court reporter. Administrative Law Judge Kerry Anderson assisted the Board in conducting the hearing and was instructed to prepare a written decision, in accordance with their deliberations.

THE RECORD

The record includes prehearing procedural documents, testimony of the witnesses and:

State's Exhibits:

1. Statement of Charges;
2. Peer Review Report;
3. Investigative Report with attachments;
4. Recording of conversation with patient BH and her husband;

[1] The "Statement of Matters Asserted" originally identified nine case in which it was alleged Respondent demonstrated professional incompetency and/or engaged in practice harmful or detrimental to the public. By the time of hearing, the State had reversed its position on two of the nine patients, leaving Respondent's actions with regard to seven patients at issue.

5. Statutes and Rules;
6. Video Deposition of Andrew Bean, M.D.

Respondent's Exhibits:

A. Written Report and Curriculum Vitae of Dr. Thomas Carroll, M.D.;
B. Letter from Dr. Brian Peterson, Wellmark Blue Cross Blue Shield with cover letter from Dr. Bill Jagiello;
C. Letter from Chinmay Dotta, M.D.;
D. Summary of slides sent to Cleveland Cliinic;
E. Pathology Quality Analysis Report 2013;
F. Pathology Quality Analysis Report 2012;
G. Letter from Dr. Jay Michael McCune;
H. Letter from Dr. J.C. Pollpeter dated December 4, 2014;
I. Letter from Dale Andres, D.O.;
J. Curriculum Vitae of Dr. Salahuddin Syed;
K. ---[2]
L. Letter from Dr. J.C. Pollpeter dated January 12, 2016.

FINDINGS OF FACT

Respondent's Education, Licensure

Respondent graduated from Mysore Medical College in India in 1993 and completed an internship in India in 1991 and 1992. He practiced in India as a family physician from 1992 through 1995. Respondent moved to the United States and completed a residency in Anatomic and Clinical Pathology at the University of Texas in Galveston from 1998 through 2002. Thereafter, he participated as a Surgical Pathology fellowship at University of Texas Southwestern Medical Center in Dallas during 2002 and 2003. Respondent served as Associate Pathologist and Medical Lab Director at the community-based outpatient veteran's clinic in College Station, Texas, from 2003 through 2007. (Respondent Testimony; Exhibit J)

Respondent was issued Iowa medical license number 37105 on March 12, 2007, and he has practiced as a pathologist in Marshalltown, Iowa, since that time. Respondent is a solo practitioner whose offices are located at the Marshalltown Medical and Surgical Center but who is not employed by that facility. (Testimony of Respondent; Exh. 1)

History of Complaints

On August 1, 2014, the Board received a complaint from Dr. Andrew Bean, M.D., a dermatologic surgeon, regarding Respondent. Dr. Bean alleged Respondent misread biopsy slides for Patient TW resulting in diagnoses of malignant

[2] Respondent did not offer an Exhibit K

melanoma in 2013 and again in 2014. Dr. Bean noted that Iowa Pathology Associates reread the slides and each actually showed an inflamed compound nevus. Iowa Pathology Associates is a private practice group, employing fourteen physicians experienced in anatomic and clinical pathology, as well as subspecialties. Dr. Bean further stated that Iowa Pathology Associates was aware of other cases in which Respondent had rendered an incorrect diagnosis. An investigation was begun and Dr. Jared Abbott of Iowa Pathology Associates was interviewed. Dr. Abbott confirmed Dr. Bean's statements and noted there were two other cases he was aware of in which Respondent's diagnoses were incorrect, Patients JH and BH.[3] Those cases involved the alleged misreading of vulvar and breast tissue biopsies, respectively. (Exh. 3, pp. 42-44)

Respondent was interviewed regarding each case on September 11, 2014 and he provided records for the three patients as well as other documents. (Exh. 3, pp. 44-47)

The Board reviewed the case on December 5, 2014, and requested that additional information be obtained for peer review. The Board asked for 20 cases including biopsies and diagnostic reports. The Board specified that it wished to review ten melanoma cases, five breast biopsies and five biopsies of vulvar tissue. A subpoena was issued to that effect. Respondent eventually submitted four melanoma cases in addition to Patient TW, eight breast tissue cases in addition to Patient BH, and eight vulvar tissue cases in addition to Patient JH. (Exh. 3, pp. 48-49)

The information provided by Respondent was sent to Dr. Joy Trueblood, M.D. for peer review. Dr. Trueblood is the Senior Pathologist and Medical Director of The Iowa Clinic, P.C. Pathology Clinic. She is Board certified in Pathology and Cytopathology and is working for special certification in Breast Pathology. During the course of that review, Dr. Trueblood raised additional questions which were submitted to Respondent and to which he responded by providing additional information. (Exh. 2, p. 9; Exh. 3, pp. 50-51)

On May 27, 2015, Dr. Trueblood issued her peer review report, opining that out of a total of twenty-four cases reviewed, Respondent failed to meet the applicable standard of care in nine. (Exh. 2)

On July 10, 2015, the Board found probable cause to file a Statement of Charges against Respondent, charging him with professional incompetency and/or practice harmful or detrimental to the public in each of the nine cases cited by Dr. Trueblood. (Exh. 1)

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[3] Patient BH is sometimes referred to in the records by her nickname "MH".

On July 17, 2015, Patient BH filed her own complaint alleging that Respondent incorrectly diagnosed her breast tissue biopsy as cancer causing her to incur additional medical bills, missed work, and emotional distress. Patient BH was interviewed and additional records collected. (Exh. 3, pp. 52-56)

By the time of hearing, two of the cases identified by Dr. Trueblood and included in the "Statement of the Matters Asserted" contained in the Statement of Charges had been resolved in Respondent's favor, leaving seven cases on which the parties presented evidence.

The Patients, Expert Testimony and Dr. Syed's Responses

Dr. Trueblood, whose qualifications are set out above, testified on behalf of the State, as did Drs. Jared Abbott, Andrew Bean, and Larry Anderson.

Dr. Thomas Carroll, M.D., Ph.D. testified on behalf of Respondent. Dr. Carroll is currently in a group practice, Pathology Medical Services of Siouxland, P.C., located at Unity Point Health, St. Luke's Regional Medical Center in Sioux City, Iowa. That group provides services for several hospitals in the region, including Floyd Valley Hospital, Burgess Memorial Hospital, Providence Medical Center, Orange City Municipal Hospital, and Horn Memorial Hospital. Dr. Carroll also serves as the Woodbury County Medical Examiner. He is certified as a Diplomat in Anatomic and Clinical Pathology by the American Board of Pathology.

1. Patient BH

Patient BH was a 56-year-old woman whose annual mammogram showed a lesion in her right breast. A needle core biopsy of the lesion was obtained on April 28, 2014. Respondent reviewed the patient's slides and diagnosed an invasive well–differentiated ductal carcinoma of the right breast. Based on his diagnosis, Respondent ordered immunohistochemical stains for estrogen and progesterone receptors and other tests. Surgical follow up was recommended. (Exh. 3, pp. 72, 79)

BH was referred to a surgeon who informed her she should undergo an immediate lumpectomy. BH sought further consultation with Drs. Scott Hambling and Konstantinos Lekkas of The Iowa Clinic for evaluation and treatment of the cancer and for reconstructive surgery. She met with both on May 6, 2014, at which time BH elected to proceed with a bilateral mastectomy followed by breast reconstruction surgery. Dr. Hambling's records show he ordered a consultation with the John Stoddard Cancer Center Tumor Board. (Exh. 3, pp. 60 – 63; Exh. 4)

John Stoddard Cancer Center's Multidisciplinary Tumor Board discussed BH's case on May 14, 2014. The participating physicians did not find evidence of malignancy and recommended sending the pathology blocks to the Mayo Clinic

for another opinion. Dr. Hambling contacted Respondent and informed him of the findings. On that same day, Respondent sent JH's slides to Mayo Clinic to be reread. Respondent also scheduled the case to be discussed at Marshalltown Medical & Surgical Center's Tumor Board on May 19, 2014. (Exh. 3, pp. 64, 67, 84-85, 99; Exh. 4)
Mayo Clinic issued its report on May 20, 2014, diagnosing a complex sclerosing lesion with usual ductal hyperplasia and microcalcifications. (Exh. 3, pp. 84-85) On that same date, Respondent authored an addendum to his pathology report amending the diagnosis to conform with that of the Mayo Clinic and adding the following comment:

> The case is reviewed for tumor board. After reviewing the case, the case was sent to Mayo Clinic for a second opinion and diagnosis is changed from invasive ductal carcinoma to complex sclerosing lesion. The changes in the diagnosis are communicated with Dr. Desotel and Dr. Hambling. Results of corrected report will be discussed by Dr. Hambling with patient.

(Exh. 3, p. 81)

BH underwent a lumpectomy performed by Dr. Hambling on May 22, 2014. Iowa Pathology Associates, P.C. reviewed the slides from the lumpectomy and issued a histopathology report confirming the diagnosis of complex sclerosing lesion. The report stated "there is no evidence of atypicality or malignancy." (Exh. 3, pp. 64-66).

An audio recording made by BH's husband of a discussion he and BH had with Respondent regarding the misdiagnosis was admitted into evidence. In response to an inquiry regarding why a second opinion was not obtained prior to making the initial diagnosis, Respondent cited to the cost of a consultation. (Exh. 4)

Dr. Trueblood reviewed BH's slides at the Board's request and, in contrast to Respondent's carcinoma diagnosis, arrived at a diagnosis of "radial scar" which term is often used interchangeably with "complex sclerosing lesion". She testified that she found the diagnosis in this case to be an easy one and one that an "average pathologist" would have been able to make. However, in her written report Dr. Trueblood relied on a textbook, which contained the following passage: "The importance of recognizing various patterns of adenosis and sclerosing lesions, and the reason they are considered together in this chapter, is that they may be mistaken for invasive carcinoma ...".[4] Dr. Trueblood noted that the condition she diagnosed is benign, although complete excision of the lesion is generally recommended if the diagnosis has been made on a needle biopsy because of the risk of associated malignancy which can be identified only after surgical excision. (Exh. 2, p. 11; Trueblood testimony)

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[4] Schmitt, Stuart J, and Collins, Laura C, *Biopsy Interpretation of the Breast,*. Copyright 2009, Lippincott Williams & Wilkins, a Wolters Kluwer business, at page 181

Dr. Trueblood also questioned Respondent's use of special stains in this case. She explained that myoepithelial cells are not present in invasive cancers and, therefore, stains can be used to look for those cells. If a stain is used and it shows that myoepithelial cells are present, the sample is not an invasive cancer. Dr. Trueblood emphasized that had Respondent ordered the appropriate stains, such as p63, to confirm or rule out cancer in BH's case, he might not have misdiagnosed cancer. On the other hand, Dr. Trueblood argued that the stains Respondent did order were for breast cancer receptors (estrogen and progesterone) and for human epidermal growth factor receptor 2 (HER2) status and that the HER2 was sent for fluorescent in-situ hybridization (FISH) analysis, all of which was unnecessary because MH did not have breast cancer. She noted these unnecessary steps added substantial cost to MH's care. (Exh. 2, p. 11; Trueblood testimony)

Dr. Trueblood emphasized that this patient might have undergone an unnecessary lumpectomy or mastectomy had her case not been reviewed further. She found Respondent failed to meet the standard of care when he misdiagnosed MH because of a substantial lack of knowledge or ability to discharge the professional obligations within the scope of a pathology practice. She also determined that Respondent's actions in this case showed a failure to possess and exercise the degree of skill, learning and care expected of a reasonable, prudent physician acting in the same or similar circumstances in this state. (Exh. 2, p. 11; Trueblood testimony)

In response to the Board's inquiry regarding this patient, Respondent admitted his initial diagnosis was incorrect. He stated; however, that he re-read BH's slides a few days later while preparing to present the case at Tumor Board and began to have second thoughts about the diagnosis. According to Respondent, he "mentally" amended the diagnosis at that time to being "suspicious of cancer". Respondent stressed that he discussed the case with BH's clinician and also sent it to the Mayo Clinic for a second opinion. He explained that complex sclerosing lesions are very difficult to evaluate and are subject to misdiagnosis. Respondent testified when he received the pathology report from the Mayo Clinic on May 20, 2014, he authored a correction to his original report, amending the diagnosis to complex sclerosing lesion with usual ductal hyperplasia and microcalcifications. Respondent also added a comment explaining the events leading up to the amended diagnosis. He noted that he discussed the amended diagnosis with the patient's clinician and surgeon. (Exh. 3, p. 81; Syed testimony)

Respondent further testified at hearing that the HER2 test and FISH analysis were requested by BH's clinician and were obtained due to that request. (Syed testimony)

Respondent emphasized that he learned from his error in this case and now requests additional immunostains and/or second opinions in these types of cases. (Exh. 3, p. 101).

Dr. Carroll, while agreeing Respondent reached an incorrect diagnosis at the outset, disagreed with Dr. Trueblood's determinations that the misdiagnosis and the use of stains demonstrated any lack of professional knowledge or a deviation from the standard of care on Respondent's part. He opined that that this type of lesion can be difficult to evaluate, especially when the pathologist has only the small amount of tissue provided by a needle core biopsy as opposed to a completely excised lesion. Dr. Carroll also emphasized that, while Dr. Trueblood opined Respondent ordered unnecessary stains, the pathologists at Mayo Clinic ordered additional stains when they reread the slides involved. (Exh. A. Carroll Testimony)

Dr. Carroll offered his opinion that Respondent did not display professional incompetence or any behavior harmful or detrimental to the public in his review and re-review of BH's case. (Exh. A; Carroll testimony)

2. ***Patient TW***

TW was 20 years old in April 2013 when her health care provider, Amanda George, ARNP, collected a skin biopsy from her back. That biopsy was reviewed by Respondent who diagnosed superficial spreading malignant melanoma (SSMM). He did not consult with any other pathologist or dermatopathologist prior to providing ARNP George with the SSMM diagnosis. (Exh. 3, pp. 45, 135-36)

TW was referred for treatment and a surgical consult was requested by her treating physician. The same biopsy material reviewed by Respondent was also read by two pathologists at McFarland Clinic in Ames, Iowa, at the surgeon's request. Those pathologists agreed with Respondent's diagnosis of SSMM. (Exh. 3, pp. 45, 136-37.)

After TW underwent an excision, she was referred to Dr. Bean, a dermatologic surgeon, for annual skin examinations. Dr. Bean noted TW's recent surgical scar and a few irregular moles during his 2013 exam. During the 2014 examination, Dr. Bean noted one irritated nevus which was removed but saw nothing atypical. (Exh. 6)

Subsequently, in July 2014, ARNP George collected a new shave biopsy from TW's back, near the site of the former biopsy. Respondent discussed the proximity of the lesions with ARNP George and the two agreed that, upon gross examination, the present biopsy material was similar in appearance to the first. Upon microscopic examination, Respondent again arrived at a diagnosis of SSMM. Once again, he did not consult with any other pathologist or

dermatopathologist prior to providing that diagnosis to ARNP George. (Exh. 3, pp. 45-46, 139-40)

ARNP George contacted Dr. Bean with TW's diagnosis. Dr. Bean questioned the diagnosis because he had examined TW only two months earlier. Dr. Bean requested and received the slide on which Respondent based his SSMM diagnosis. When he viewed the slide, Dr. Bean believed it to show an irritated nevus and not SSMM. (Exhibit 6)

Dr. Bean sent the slide from TW's latest biopsy to Iowa Pathology Associates, P.C. to be reread. Dr. Jared Abbott, M.D, Ph.D, who is certified in Anatomic Pathology and Dermatopathology, reviewed TW's slide. Dr. Abbott found nothing in the sample which would point to melanoma. He determined the slide showed an inflamed compound nevus. Because his diagnosis conflicted with Respondent's diagnosis, Dr. Abbott consulted with four of his colleagues, each of whom agreed the slide was not SSMM but an inflamed compound nevus. (Abott testimony; Exh. 3, p. 142; Exh. 6)

Dr. Abbott reported his findings to Dr. Bean who then began to question TW's 2013 SSMM diagnosis. Dr. Bean obtained the slides from the 2013 biopsy which looked to him to be identical to the slide from the 2014 biopsy. Dr. Bean sent these slides to Dr. Abbott for review as well. (Exh. 6)

Dr. Abbott reviewed the slides from the 2013 biopsy and, once again, arrived at a diagnosis of inflamed compound nevus. He shared these slides with the same four colleagues previously consulted and, once again, each concluded that the SSMM diagnosis was incorrect and that the slides showed an inflamed compound nevus. (Abbot testimony; Exh. 3, p. 141)

Based on Dr. Abbott's diagnosis, Dr. Bean alerted TW's mother that TW did not have melanoma and she avoided a second surgery. (Exh. 6)

At hearing, Dr. Bean expressed his concerns with Respondent's misdiagnosis in TW's case. Bean explained that a diagnosis of melanoma often makes it difficult for the patient to obtain health insurance and often he or she cannot obtain life insurance. Dr. Bean also explained that persons diagnosed with melanoma are prohibited from donating tissue or blood. Finally, Dr. Bean testified to his fear that, if Respondent misdiagnosed an inflamed compound nevus as malignant melanoma, that he might also be misdiagnosing malignant melanomas as inflamed compound nevi, thereby potentially exposing patients to the risk of developing metastatic melanoma. (Exh. 6)

Dr. Trueblood testified that neither of the biopsy specimens collected from TW showed features of malignant melanoma. She noted there was no upward migration of atypical melanocytes or Pagetoid spread of atypical melanocytes. Dr. Trueblood explained the melanocytes in TW's biopsies showed no evidence

of cytological atypia. Dr. Trueblood also took issue with the fact Respondent ordered a Melan-A stain, which, while it might have been appropriate had the biopsies shown malignant melanoma, was unnecessary since the correct diagnosis was an inflamed compound nevus. (Exh. 2, p. 16; Trueblood testimony)

Dr. Trueblood emphasized the emotional strain placed on a patient once given a diagnosis of malignant melanoma. She also noted that such a diagnosis might well result in a wider excision of the biopsy site, a regional lymph node excision, and chemotherapy; all unnecessary for an inflamed compound nevus. (Exh. 2, p. 16; Trueblood testimony)

Drs. Trueblood, Bean, and Abbot all testified to the difficulty of making a diagnosis of malignant melanoma. Dr. Trueblood wrote in her peer review report for the Board:

> In my practice, EVERY case I think is a malignant melanoma goes out for second (and sometimes third) opinion; regardless of how certain I am that the lesion is indeed a malignant melanoma. I feel that the practice of skin pathology (Dermatopathology) is very difficult when it comes to accurately classifying atypical melanocytic proliferations, such as malignant melanoma and dysplastic nevi. Without special training I believe it's best to get second opinions on these cases, however that is my opinion and may not be shared by all pathologists.

(Exh. 2, p. 16)

Likewise, while Dr. Bean testified he was not an expert in pathology, he asserted that the diagnosis of an inflamed nevus is not a difficult one to make. Dr. Bean did, admit, however, that the subspecialty of dermatopathology was developed specifically because of the difficulty in diagnosing melanomas. He noted that, in his practice, he sees "problem after problem" with the diagnoses provided by general pathologists and that, as a result, he will not accept a diagnosis from a general pathologist without confirmation by a specialist. (Exh. 6)

Dr. Abbott noted that the practice of pathology involves, at best, the subjective interpretation of objective data and, at times, less than objective data. Dr. Abbott stated that malignant melanoma is a particularly difficult diagnosis and urged that confirmation of that diagnosis could and should be had through consultation with a pathology group with subspecialty expertise such as the pathology group at Mayo Clinic. (Abbott testimony)

In response to the complaint regarding this patient, Respondent noted that his 2013 diagnosis of SSMM was confirmed by the Ames Pathology Group who reviewed the biopsy at that time at the request of the patient's surgeon. He

stressed that he read the 2014 biopsy with the knowledge this patient had been diagnosed with SSMM and that diagnosis had been confirmed the previous year. He also noted that the 2014 biopsy was taken very close to the site of the 2013 biopsy. Respondent noted that this information caused him to lean towards a SSMM diagnosis. He also explained that, since the biopsy was from TW's back, an excision with a wider margin would not lead to any cosmetic defects. He noted he was aggressive in this case because he did not want TW to come back with metastatic melanoma. He stressed the difficulty of diagnosing pigmented skin lesions. (Exh. 3, p. 144)

At hearing, Respondent testified that he remains convinced TW's 2014 biopsy showed SSMM. (Syed testimony)

Dr. Carroll expressed a different opinion in TW's case. He stressed that the 2013 SSMM diagnosis had been confirmed after the slides were reread by the Ames Pathology Group and that fact, along with the histology of the 2014 biopsy, would have led him to classify the latter specimen as, at the very least, an atypical compound melanocytic proliferation which would not rule out melanoma. Dr. Carroll stated that his review of the specimen revealed extensive lymphocytic reaction in the dermis which, in some cases, can mask an infiltrating tumor. He noted that, in his practice, this sample would have been sent out for a consultation with a Dermatopathologist. However, once again, Dr. Carroll found no professional incompetency or harm to the public in Respondent's actions with regard to this case. (Exh. A; Carroll testimony)

3. ***Patient DT***

The file for Patient DT was one of those requested by the Board and provided by Respondent for review. DT was an 82-year-old female who presented with swollen lymph nodes under her right arm. She underwent a core needle biopsy on August 11, 2014. That biopsy failed to provide a sufficient amount of viable tissue from which to arrive at a definitive diagnosis but Respondent was of the opinion that the sample was "suggestive but not diagnostic of metastatic melanoma." (Exh. 3, pp. 179, 186)

On August 26, 2014, a right axillary lymph node excisional biopsy was performed on DT and the sample was sent to Respondent. Because of the small amount of viable tissue, Respondent prepared a portion of the material for flow cytometry and the remainder in touch preparations, a method by which a thin layer of cells is distributed on a slide for examination. There was insufficient tissue for a frozen section, which consists of a thin slice of tissue cut from a frozen specimen. Respondent ordered eleven special stains and arrived at a diagnosis of malignant melanoma. (Exh. 3, pp. 176, 179-80).

Dr. Trueblood reviewed this file and expressed no concerns about Respondent's final diagnosis; however, she opined that his use of eleven special stains to rule out other forms of cancer was unnecessary. Dr. Trueblood testified that the majority of pathologists are able to diagnose melanoma through touch preparations although many would prefer a frozen section to rely on. She opined that the touch preparations in this case showed such obvious signs of malignant melanoma that no stains were necessary unless the patient had a history of other cancer. Dr. Trueblood testified, if that were the case, a single, inexpensive stain to confirm the diagnosis would have been appropriate. She stated that Respondent's use of eleven stains suggested a lack of knowledge both as to the appearance of malignant melanoma and as to the appropriate use of special stains. She emphasized the unnecessary expense added to DT's treatment because of the use of these stains. (Exh. 2, pp. 17-18; Trueblood testimony)

Respondent defended his use of stains in this case. He stressed that this patient had no clinical history of cancers. He further noted that he does not have the ability to do stains in his own lab and specimens must be sent out for staining. Respondent explained that process involves several days and patients are often anxious to receive a diagnosis. He noted that he orders all stains he might need when he sends slides out so as to avoid having to send them out a second or third time. Respondent reported he has never had an insurer question his use of stains and that he is of the opinion that the number and type of stains to be used are at the discretion of the physician. He stressed that his diagnosis of malignant melanoma was correct in this case and that a previous punch biopsy performed by an outside facility on a skin lesion on DT's right arm had been misdiagnosed as benign. After Respondent's diagnosis that facility reviewed the specimen from the punch biopsy and amended its diagnosis accordingly. (Exh. 3, p. 179; Syed testimony)

Dr. Carroll also agreed with Respondent's diagnosis. Dr. Carroll also stressed that it is the pathologist's prerogative as to how many stains to order. He noted that Respondent received DT's slides without a medical history. Dr. Carroll admitted that he might have begun with fewer stains but he appreciated that Respondent might have felt the need to order additional stains in order to rule out other types of malignancies. Dr. Carroll was unwilling to deem the ordering of multiple special stains a deviation from the standard of care. (Exh. A; Carroll testimony)

Dr. Carroll further agreed with Respondent that the misreading of DT's previous punch biopsy by an outside facility demonstrates the difficulty of diagnosing melanocytic lesions. (Exh. A; Carroll testimony)

4. Patient DF

The file for Patient DF was provided at the Board's request. DF was a 72-year-old male with a clinical diagnosis of malignant melanoma. On September 24,

2014, he underwent an excision of left forearm skin and removal of left sentinel lymph nodes. Intraoperative frozen sections were prepared from the lymph node material and Respondent ordered two special stains, Melan A and HMB 45. Respondent issued a report finding the lymph node material negative for metastatic melanoma. (Exh. 3; pp. 202-204)

Once again, Dr. Trueblood did not take issue with the diagnosis in this case. Instead, she expressed her opinion that Respondent ordered inappropriate immunohistochemical stains on the lymph node samples. In her peer review report Trueblood wrote: "There is no agreed upon protocol to do HMB-45 and/or Melan-A on sentinel lymph nodes to look for metastatic melanoma cells. She called the use of the stains unnecessary and stated: This just adds cost to the patient. Melanoma cells are very large and easy to see, therefore making these stains necessary." (Exh. 2, p. 18-19)

At hearing, Respondent again argued that the use of stains is the prerogative of the doctor and that the stains he used in this case were appropriate. Respondent stressed, that, once again, his diagnosis in this case was not questioned by Dr. Trueblood. (Syed testimony)

Dr. Carroll, supported Respondent's use of stains in DF's case. He noted that, in his own practice, he uses the same strategy employed by Respondent to evaluate the presence of microscopic metastases in lymph nodes. He explained that the American Joint Committee on Cancer (AJCC) Staging Handbook recommends the use of stains for the detection of micrometastases and considers it acceptable to classify lymph node positive metastases based solely on staining of melanoma-associated markers. (Exh. A; Carroll testimony)

Dr. Trueblood countered that both of the special stains ordered by Respondent are specific for melanoma. She noted that the AJCC Melanoma Taskforce has recommended using one specific stain and one sensitive stain. Stains which are specific for melanoma are useful to avoid false positives while stains which are sensitive for melanoma are useful to avoid false negatives. According to the AJCC using only specific markers can lead to missing up to 15% of malignant melanomas. Dr. Trueblood remained convinced Respondent's actions in ordering the stains he used violated the standard of care. (Trueblood testimony)

5. ***Patient JH***

This file was also submitted by Respondent at the Board's request. JH was a 49-year-old female who underwent a punch biopsy of the left labia on July 15, 2014. The specimen was delivered to Respondent who issued a pathology report diagnosing keratoacanthoma (KA). Under the "COMMENT" portion of the report, Respondent noted "The specimen shows changes of a well-differentiated squamous cell carcinoma." (Exh. 3, p. 211)

The slides examined by Respondent were subsequently reread by Dr. Larry Anderson of Iowa Pathology Associates who confirmed his diagnosis with Drs. Jared Abbott and Timothy Drevyanko. Dr. Anderson arrived at a diagnosis of a well-differentiated squamous cell carcinoma with an .85 cm depth of invasion. (Exh. 3, p. 212)

Dr. Trueblood reviewed this file and arrived at the opinion that Respondent's diagnosis of KA in this case demonstrated a lack of professional competency and knowledge. Dr. Trueblood emphasized the correct diagnosis here was well-differentiated squamous cell carcinoma. She explained that a KA, as diagnosed by Respondent, is a lesion of sun-exposed skin, generally found in the elderly. It is shaped like a wart and protrudes up from the skin surface whereas this lesion was not protruding and was located on the vulva. Dr. Trueblood acknowledged that some authorities believe a KA is a form of well-differentiated squamous cell carcinoma but she opined the term should never be used to describe the type of lesion involved in this case. (Exh. 2, p. 21)

At hearing, Dr. Trueblood further explained that a KA is marked by a dome shape and a keratin core. The sample in this case did not show those characteristics. Dr. Trueblood stated, however, even more telling was the location of the tumor: KAs are found on skin which is exposed to the sun and the fact that this sample was of vulvar tissue should have led Respondent to the conclusion it was not a KA. Dr. Trueblood noted that while vulvar KAs have been reported in the literature, they are extremely rare. (Trueblood testimony)

Dr. Trueblood testified that the misdiagnosis in this case could have resulted in the patient receiving inappropriate treatment. She explained that KAs do not usually metastasize and excision of the lesion with an adequate margin is the accepted treatment for such a tumor. Squamous cell carcinoma, on the other hand, may develop lymph node metastasis and the accepted treatment is therefore much more aggressive, and may involve removal of lymph nodes and chemotherapy. Dr. Trueblood offered her opinion that Respondent's misuse of terminology demonstrated a lack of the substantial knowledge or ability to discharge the obligations of a pathologist. (Exh. 2, p. 21; Trueblood testimony)

Dr. Larry Anderson is a Surgical Pathologist with Iowa Pathology Associates. He testified at hearing that he was asked to review JH's biopsy because of a concern the KA diagnosis provided by Respondent was incorrect. Dr. Anderson noted that while a KA can look quite similar to squamous cell carcinoma; KAs are not found on the vulva. He testified that he shared this biopsy with colleagues who had 250 years of combined experience and not one had ever seen a KA in vulvar tissue. Dr. Anderson disagreed with the suggestion that this was simply a matter of semantics. He stated that, while one might use the terms KA and squamous cell carcinoma interchangeably if one is speaking of skin on the arm or another sun-exposed area, that is simply not the case with vulvar tissue. Dr. Anderson also emphasized that this was a deeply invasive tumor, .85 cm,

requiring much more aggressive action than would be required for a KA. (Exh. 3, p. 212; Anderson testimony)

Dr. Abbott also testified at hearing that he reviewed the slides from JH's biopsy at Dr. Anderson's request. He agreed with Drs. Anderson and Trueblood that KAs are not found in vulvar tissue and are restricted to sun-exposed skin. Dr. Abbott expressed his opinion that this was not a difficult diagnosis to make. (Abbott testimony)

Respondent argued that the difference between his diagnosis and that of Iowa Pathology Associates was only a matter of semantics. He testified that some authorities use the terms KA and squamous cell carcinoma interchangeably. He stressed that he used the term "well differentiated squamous cell carcinoma" in the comment section of his report. Respondent testified that, while KAs are generally found on sun-exposed skin, there have been reports in the literature of vulvar KAs. (Syed testimony)

In response to questions as to why he did not report the depth of the lesion, Respondent explained that he did not do so because the sample was from a punch biopsy. He noted that he recommended the entire lesion be excised which would allow him to make a concrete diagnosis of the sample and the depth of the tumor. (Exh. 3, p. 214; Syed testimony)

Dr. Carroll agreed with Respondent and refused to characterize Respondent's conclusions as a misdiagnosis. He testified the dispute in this case was as to terminology only and did not rise to a breach of the standard of care. He noted that, in addition to providing the diagnosis of KA, Respondent authored a comment in his report stating that the biopsy showed a well-differentiated squamous cell carcinoma. Dr. Carroll testified that many authorities consider a KA to be a low grade invasive, well-differentiated squamous cell carcinoma, while others regard it as a unique lesion. Dr. Carroll emphasized that even though Respondent did not refer to the depth of the lesion, he recommended complete excision. Dr. Carroll opined that Respondent met the standard of care in this case. (Exh. A; Carroll testimony)

6. Patient GK

Again, this file was provided by Respondent for review at the Board's request. GK was a 70-year-old female who underwent a right vulva punch biopsy on July 1, 2014. The sample was delivered to Respondent who noted pigmented cells within the epidermis. Respondent ordered five stains to confirm the diagnosis and rule out Paget's disease. All stains were negative and Respondent arrived at a diagnosis of condyloma acuminatum with low grade vulvar dysplasia. (Exh. 3, p.229).

Dr. Trueblood disagreed with Respondent's diagnosis in this case. She described her findings as "[h]igh grade squamous intraepithelial lesion characterized by severe squamous dysplasia" and noted "[t]his lesion requires complete excision to rule out invasive squamous cell carcinoma. A wider excision to include negative margins should have been performed." (Exh. 2, p-. 21-22; Trueblood testimony)

Dr. Trueblood offered her opinion that Respondent became sidetracked when he saw pigmented cells in the dermis and dying squamous cells in the epidermis. Dr. Trueblood testified she thinks these findings led Respondent to believe he needed to rule out Paget's disease and malignant melanoma, which led to the ordering of the five special stains. She explained that, in her opinion, the dying squamous cells looked nothing like Paget's cells and the pigmented cells in the epidermis did not appear at all atypical as they would in a malignant melanoma. Dr. Trueblood stated both the ordering of the stains and the misdiagnosis showed a deviation from the standard of care on Respondent's part. She emphasized this was not a benign lesion and the proper diagnosis, high grade squamous dysplasia, requires the excision of additional tissue to rule out invasive squamous cell carcinoma. (Exh. 2, pp. 21-22; Trueblood testimony)

In response to questions about his diagnosis and the use of stains in this case, Respondent noted that he saw large epithelial cells with prominent nuclei in the specimen which may be seen in Paget's disease as well as other diseases. Respondent explained he ordered stains to rule out Paget's disease and melanoma in-situ. (Exh. 3, p. 231; Syed testimony)

Dr. Carroll agreed with Dr. Trueblood that Respondent arrived at a misdiagnosis in this case; however, he did not agree that the misdiagnosis or the use of stains constituted a violation of the standard of care. Dr. Carroll opined that the histology warranted the use of stains to rule out Paget's disease and melanoma and he did not believe the failure to report moderate to severe dysplasia would have resulted in improper management of GK's care. (Exh. A; Carroll testimony)

7. ***Patient SG***

Patient SG's files were also provided to the Board at its request. SG was a 74-year-old female who underwent a vulvar punch biopsy on August 11, 2014. Respondent reviewed the specimen and arrived at a diagnosis of lichen sclerosus, a nonmalignant condition. (Exh. 3, p. 248)

Dr. Trueblood arrived at a diagnosis different from that of Respondent's lichen sclerosis diagnosis. She found "[s]kin showing foamy histiocytes, chronic dermal inflammation, and hemosiderin deposition, with a subepidermal vesicle." She believed the changes represented a reaction to an injury which could be from a ruptured cyst or gland. This is also a nonmalignant condition; however, the

patient would be managed differently than would a patient with lichen sclerosis. (Exh. 2, pp. 22-23)

At hearing, Dr. Trueblood emphasized that she saw no features of lichen sclerosis in her review of the slides. She explained that lichen sclerosis features inflammation running parallel to the epidermis and that was not the case in SG's specimen. She also testified that the pathology report issued by Respondent did not contain his microscopic findings so she was unable to determine exactly what features he saw that led him to his diagnosis. Dr. Trueblood found Respondent did not meet the standard of care in this case. (Trueblood testimony)

Respondent noted that he found this to be a "rather straight forward case". He stated that his diagnosis fit SG's age, the clinical information supplied, and the histomorphology. At hearing, he pointed out that, even though Dr. Trueblood criticized his diagnosis, she did not provide a definitive diagnosis herself but only a descriptive diagnosis. Respondent explained that he looks at possible cancer cases, such as this, first thing in the morning when his mind is fresh. After he is able to rule out a malignancy, as in SG's case, he waits for the surgical biopsy to correlate his initial diagnosis. Once again, Respondent stressed that SG did not have a malignant lesion. (Exh. 3; Syed testimony)

Dr. Carroll disagreed with Dr. Trueblood's diagnosis. He found Respondent's diagnosis to be more appropriate. Dr. Carroll opined that the biopsy "most likely represents a hypertophic variant of lichen sclerosis et atrophicus, which has some evidence of trauma or irritation in the recent past." He stressed that he did not believe Respondent arrived at a misdiagnosis in this case or that he failed to meet the standard of care. (Exh. A; Carroll testimony)

Additional Evidence

Dr. Trueblood noted in her peer review report and at hearing that, while she did not believe Respondent acted willfully, she found an obvious lack of proper terminology and a lack of the knowledge necessary to arrive at a correct diagnosis in reviewing these cases. She admitted that all pathologists make mistakes, however, she emphasized that the best knowledge a pathologist can have is that of what he or she does not know. Dr. Trueblood stressed the importance of knowing one's limitations and seeking second opinions when one is faced with those limitations. (Exh. 2, p. 27; Trueblood testimony)

Respondent testified at hearing that he practices alone. He reviews between 3,000 and 5,000 cases each year. Respondent stated that since he is the only pathologist in Marshalltown, he "has to know everything" but he also stressed that he knows his limitations. Respondent testified he does not do pap smears, autopsies or bone marrow biopsies because he will not do something he is not sure of. Respondent noted during his time in Marshalltown he has never had a surgeon disagree with a diagnosis of his. (Syed testimony)

Respondent stressed that he is committed to providing quality care to his patients. In an effort to do so, he established the Tumor Board which now meets every month to review and discuss pathology cases. He also maintains quality assurance data: he receives reports back from patients who have been referred on to specialists and he keeps records and reports on those cases. Respondent submitted pathology quality analysis reports he compiled for the years 2012 and 2013. The 2012 report reflects that, out of 229 cases reviewed, there were no "major" disagreements with his efforts, only two "moderate" disagreements, neither of which involved potential harm to the patient and thirteen "minor" disagreements that involved terminology or billing code errors. (Exh. E) The 2013 report involves 132 cases, of which there were no "major" disagreements, five "moderate" disagreements that did not involve potential harm to the patient, and five "minor" disagreements as to terminology or billing codes. (Exh. F)

Respondent also noted that he was out of the country when Marshalltown Medical & Surgical Center (MMSC) was initially notified of a complaint against him and that, in his absence, 30 of his cases were randomly selected for review by pathologists at Mayo Clinic. Of those 30 cases, there was agreement in 28. Based on the review, the Medical Staff President at MMSC expressed his confidence that Respondent was providing appropriate care. (Exh. H)

Random review of Respondent's cases has been ongoing. Thirty-seven of Respondent's cases were sent to Pathology Associates of Central Iowa at Mercy Medical Center in Des Moines. Those cases represented a variety of biopsies reviewed by Respondent from July 10, 2015 through July 31, 2015. Dr. Dale Andres, D.O., performed the review and found no discrepancies. (Exh. I) In September 2015, 30 of Respondent's 236 slides were sent to the Cleveland Clinic for a review of 12% of his cases. In October 2015, 17 of 360 slides were sent for a review of 4.72% of Respondent's cases and in November 2015, 17 of 387 slides, were sent for review, constituting 4.39% of Respondent's cases. The samples included masses, colon, skin, breast, esophagus and endometrial tissues. Cleveland Clinic reported a 100% correlation with Respondent's diagnoses each month. (Exh. L) Finally, a quality improvement review conducted by Dr. Brian Peterson, M.D., on behalf of Wellmark BC/BS of Iowa in October 2015 resulted in the reviewing pathologist stating: "I find nothing in this work with which to disagree." (Exh. B)

CONCLUSIONS OF LAW

Respondent is charged with professional incompetency and/or practice harmful or detrimental to the public. As pointed out by Respondent, the State has the burden of establishing these charges by a preponderance of the evidence.[5]

[5] *Eaves v. Iowa Bd. Of Medical Examrs.*, 467 N.W.2d 234, 237 (Iowa 1991).

The Board's rules define the term "professional incompetency" as including, but not being limited to:

> *a.* Willful or repeated gross malpractice;[6]
> *b.* Willful or gross negligence;[7]
> *c.* A substantial lack of knowledge or ability to discharge professional obligations within the scope of the physician's or surgeon's practice;[8]
> *d.* A substantial deviation by the physician from the standards of learning or skill ordinarily possessed and applied by other physicians or surgeons in the state of Iowa acting in the same or similar circumstances;[9]
> *e.* A failure by a physician or surgeon to exercise in a substantial respect that degree of care which is ordinarily exercised by the average physician or surgeon in the state of Iowa acting in the same or similar circumstances;[10]
> *f.* A willful or repeated departure from or the failure to conform to the minimal standard of acceptable and prevailing practice of medicine and surgery or osteopathic medicine and surgery in the state of Iowa;[11]
> *g.* Failure to meet the acceptable and prevailing standard of care when delegating or supervising medical services provided by another physician, health care practitioner, or other individual who is collaborating with or acting as an agent, associate, or employee of the physician responsible for the patient's care, whether or not injury results.[12]

The rules define the term "practice harmful or detrimental to the public" as including, but not being limited to:

> ... the failure of a physician to possess and exercise that degree of skill, learning and care expected of a reasonable, prudent physician acting in the same or similar circumstances in this state, or when a physician is unable to practice medicine with reasonable skill and safety as a result of a mental or physical impairment or chemical abuse.[13]

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[6] 653 IAC 23.1(2)(a).
[7] 653 IAC 23.1(2)(b).
[8] 653 IAC 23.1(2)(c).
[9] 653 IAC 23.1(2)(d).
[10] 653 IAC 23.1(2)(e).
[11] 653 IAC 23.1(2)(f).
[12] 653 IAC 23.1(2)(g).
[13] 653 IAC 23.1(3).

The charges brought against Respondent involve two separate areas: the alleged misuse of immunohistochemical stains and allegations of misdiagnoses.

Misuse of Immunohistochemical Stains:

The Board is unconvinced that the evidence presented regarding Respondent's use of special stains meets the definitions of either professional incompetency or practice harmful or detrimental to the public. The State argues that the evidence shows a lack of appropriate knowledge as to when and which special stains to use. The contention is that in some cases stains were not necessary because the proper diagnosis was obvious from a review of the biopsy slides while in other cases the stains ordered were inappropriate given the proper diagnosis, which Respondent failed to reach.

The Board is concerned that the State's position ignores the realities of Respondent's practice. He is a general pathologist in a solo practice. He is not a subspecialist and he does not have colleagues with whom to consult. He also lacks the ability to use immunohistochemical stains in his own lab and is required to send specimens outside for staining which takes time. Respondent testified it is his practice to order all stains he thinks might possibly be necessary the first time he sends a slide out so that his patients will get their results more quickly. The evidence shows that the number and type of stains utilized is generally at the discretion of the physician. Respondent argues that this is borne out by the fact no insurance company has questioned the number stains ordered by Respondent. The Board finds that the real question raised by these allegations rests with Respondent's diagnostic abilities.

Misdiagnosis:

Questions surrounding Respondent's competency to diagnose are not easily answered.

Patient SG:

There was a divergence in the evidence surrounding Respondent's diagnosis in SG's case. Dr. Trueblood opined that Respondent arrived at an incorrect diagnosis and stressed that she could not even determine how he arrived at his conclusions because he failed to describe his microscopic findings in the pathology report. Dr. Carroll, on the other hand, found Respondent's diagnosis to be more appropriate than Dr. Trueblood's. None of the experts gave a definitive diagnosis but all agreed the lesion was not malignant.

The Board was faced with two equally credible experts who arrived at differing views after reviewing the same slides on which Respondent based his diagnosis. This fact highlights other testimony at hearing describing pathology as a discipline in which two similarly trained pathologists can disagree on a diagnosis

without either violating the standard of care. It also leads the Board to the conclusion that the State failed in its burden to prove Respondent failed to meet the appropriate standard of care in SG's case or that he engaged in practice harmful or detrimental to the public.

The absence of microscopic findings in SG's case is concerning. As will be noted below, the Board is of the opinion that other of Respondent's reports are lacking in precision. While it is not believed the inattention to detail demonstrated in these pathology reports rises to a level worthy of sanction, the Board urges Respondent to exercise more care and attention in the communication of his findings.

Although there was a difference of opinion regarding Respondent's diagnosis in SG's case, there was clearly a preponderance of the evidence to demonstrate that Respondent arrived at incorrect diagnoses in the cases of patients BH, TW, JH, and GK. The question in these cases becomes whether Respondent's errors constitute professional incompetency and/or practice harmful or detrimental to the public as defined by rule.

Patient BH:

Respondent admitted his error with regard to BH's biopsy but insisted he recognized the misdiagnosis himself, "mentally" amended his conclusions and sent the sample to the Mayo Clinic to be reread. Respondent contended when he received Mayo's report he amended his report in writing to reflect the events occurring after the initial, incorrect diagnosis as well as the corrected diagnosis. The Board is skeptical of that explanation given that Dr. Hambling, BH's surgeon, contacted Respondent and informed him of the misdiagnosis on the same day Respondent sent the sample out for consultation. Further, the Board finds Respondent's testimony regarding his "mental" amendment to his original pathology report questionable. It appears more likely Respondent requested a consultation after he was made aware by Dr. Hambling that he had misdiagnosed BH.

Patient TW:

TW's case is a difficult one. The State's experts each testified that TW's biopsy showed no signs of melanoma and should have been easily diagnosed as an inflamed compound nevus; however, each of them also emphasized the difficulty in diagnosing melanomas, with Dr. Bean even stating his group will not accept such diagnoses from general pathologists without confirmation by a dermatopathologist. The latter testimony is borne out by the fact Respondent's earlier SSMM diagnosis in 2013 was confirmed by an outside pathology group even though it was later determined by Dr. Abbott and his colleagues to be incorrect.

The Board notes, however, that the consultation with the pathology group who confirmed Respondent's diagnosis in 2013 was at the request of TW's treating physician: it was not arranged for by Respondent. Nor did Respondent seek a second opinion when he made the SSMM diagnosis in 2014. Yet Respondent fully agreed with the other physicians who testified at hearing as to the complexity of an accurate diagnosis in suspected melanoma cases.

Patient JH:

The Board does not accept Respondent's and Dr. Carroll's portrayals of the dispute surrounding JH's diagnosis as one of semantics only. The evidence is clear that the lesion in this case was not a KA which is nearly always found on sun-exposed skin. The evidence is also clear that, while some authorities believe a KA is a form of well-differentiated squamous cell carcinoma and use the terms interchangeably when referring to a lesion on sun-exposed skin, the term "KA" is not used to refer to such a lesion in vulvar tissue. Further, while the literature does contain a few instances of KAs on the vulva, those occurrences are exceedingly rare and happening upon such a case would be remarkable. Respondent's diagnosis in this case demonstrates an obvious lack of knowledge and a departure from the standard of care applicable to Respondent. The Board finds that Respondent's actions in this case amount to professional incompetency and practice harmful and detrimental to the public.

Dr. Syed's insistence that he used the term "well-differentiated squamous cell carcinoma" in the comment portion of his report cannot salvage his diagnosis. The purpose of a pathology report is to accurately transmit the information necessary for a patient's proper treatment. A complete and accurate report is crucial to attaining that goal. The diagnosis portion of a pathology report represents the "bottom line" while the "comments" section is reserved for the explanation of any tangential issues which the pathologist may have recognized. In JH's case the proper diagnosis was a well-differentiated squamous cell carcinoma—not a KA—and that term should have been used in the diagnosis, rather than in the comment portion of the report. The accepted treatments for the two lesions are markedly different and the use of the improper terminology in the diagnosis portion of the report, especially considering how invasive this lesion was, could have resulted in mismanagement of the patient's care.

Patient GK:

Both the State's and Respondent's experts agree that Respondent arrived at an incorrect diagnosis in GK's case with regard to the level of dysplasia; however the evidence is conflicting as to whether that misdiagnosis constitutes a breach of the standard of care. The Board is, once again, faced with two, equally credible experts, who have expressed contradictory opinions leading to the conclusion there is not a preponderance of the evidence to support one position over the other.

All of the experts testified that, while perfection is a worthy goal, all pathologists are subject to error. Thus, with the exception of JH's case, the Board does not believe Respondent's other misdiagnoses, in themselves, represent a pattern which rises to the level of professional incompetency or practice harmful or detrimental to the public. This result is bolstered by the fact many of Respondent's cases have been subject to review over the years without a major disagreement as to his diagnoses.

Although the Board does not believe that Respondent's failure to arrive at the correct diagnosis in the cases of BH, TW, and GK is sufficient, in itself, to establish a sanctionable lack of knowledge or ability under the rules, the evidence clearly establishes that the failure to obtain a second opinion in cases of suspected melanoma is. Every pathologist who testified, excepting Respondent, noted the difficulty of such a diagnosis and each one stated that he or she would seek consultation prior to making a final diagnosis. The evidence shows; however, that Respondent failed to seek second opinions even though he agreed as to the complexity of a melanoma diagnosis. The Board believes Respondent's testimony that he leans toward aggressive diagnoses in cases of possible melanoma, demonstrates a lack of familiarity with the subject that, while not professional incompetency in its own right, triggers the need for consultation with pathologists more knowledgeable in the area in order to avoid incompetency and/or practice harmful or detrimental to the public as defined by rule.

Conclusion

The Board concluded that the preponderance of evidence demonstrates that Respondent demonstrated professional incompetency and engaged in practice harmful or detrimental to the public in two regards:

- Respondent misdiagnosed a well-differentiated squamous cell carcinoma in vulvar tissue as a keratoacanthoma; and,
- Respondent failed to seek consultations in cases of suspected melanoma.

Sanctions

The Board recognized that there was significant conflicting testimony regarding Respondent's professional competency and the Board seriously considered the State's request to send Respondent for a comprehensive competency evaluation at a nationally recognized assessment program. However, the Board concluded that the public's interest is served by a period of close monitoring of Respondent's pathology practice.

DECISION AND ORDER

THEREFORE IT IS HEREBY ORDERED THAT:

1. **Citation and Warning:** Respondent is hereby **CITED** for engaging in professional incompetence and practice harmful and detrimental to the public in his pathology practice when he misdiagnosed a well-differentiated squamous cell carcinoma in vulvar tissue as a keratoacanthoma and failed to seek consultations in cases of suspected melanoma. Respondent is hereby **WARNED** that such practice in the future may result in further disciplinary action against his Iowa medical license.

2. **Outside Audits:** Respondent shall arrange for continuing audits of 5% of his cases by an outside pathology laboratory approved by the Board. Respondent shall submit a list of all of his cases to the Board each quarter. From that list, the Board shall select 5% quarterly. Respondent shall provide the Board copies of the records for each patient selected and the Board shall submit the selected records to the auditing entity for review. The auditing entity shall submit a report of its audit findings to the Board on a quarterly basis. This requirement shall remain in effect until such time as Respondent demonstrates his competency to the satisfaction of the Board and the Board provides written approval to discontinue this requirement.

3. **Suspected Melanoma:** Respondent shall, in all cases of suspected melanoma, obtain a consultation with a Board-approved, board-certified Dermatopathologist prior to issuing any pathology report. This requirement shall remain effective until such time as the Board determines Respondent is competent to diagnose melanomas and the Board provides written approval to discontinue this requirement.

4. **Professional Paper:** Respondent shall author a professional paper discussing the diagnostic criteria for well-differentiated squamous cell carcinoma and keratoacanthoma in vulvar tissue and submit the paper to the Board for approval.

IT IS FURTHER ORDERED that Respondent shall obey all federal, state and local laws, and all rules governing the practice of medicine in Iowa.

IT IS FURTHER ORDERED, in accordance with 653 IAC 25.33, that Respondent shall pay a disciplinary hearing fee of $75.00. In addition, Respondent shall pay any costs certified by the executive director and reimbursable pursuant to subrule 25.33(3). All fees and costs shall be paid in the form of a check or money order payable to the state of Iowa and delivered to the department of public health, within thirty days of the issuance of a final decision.

K. Ulveling MD

April 8, 2016
Date

Kyle Ulveling, M.D., Hearing Panel Chair
Iowa Board of Medicine
400 S.W. 8th Street, Suite C
Des Moines, Iowa, 50309-4686

cc: Connie Diekema
Finley Law Firm
699 Walnut Street, Ste. 1700
Des Moines, Iowa 50309 (CERTIFIED)

Julie Bussanmas, Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319 (LOCAL)

Judicial review of the board's action may be sought in accordance with the terms of the Iowa administrative procedure act, from and after the date of the Board's order.

BEFORE THE IOWA BOARD OF MEDICINE

****

IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST

SALAHUDDIN SYED, M.D., RESPONDENT

FILE No. 02-14-406

****

CONTINUANCE ORDER

****

COMES NOW the Iowa Board of Medicine and files this Continuance Order.

IT IS HEREBY ORDERED that the contested case hearing currently scheduled on November 19-20, 2015, is continued until further order.

This order dated October 26, 2015.

IOWA BOARD OF MEDICINE

Mark E. Bowden, MPA
Executive Director
400 SW 8th Street, Suite C
Des Moines, Iowa 50309-4686

BEFORE THE IOWA BOARD OF MEDICINE

****

IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST

SALAHUDDIN SYED, M.D., RESPONDENT

FILE No. 02-14-406

****

STATEMENT OF CHARGES

****

COMES NOW the Iowa Board of Medicine on July 10, 2015, and files this Statement of Charges pursuant to Iowa Code section 17A.12(2). Respondent was issued Iowa medical license number 37105 on March 12, 2007. Respondent's Iowa medical license is active and will next expire on March 1, 2016.

A. TIME, PLACE AND NATURE OF HEARING

1. Hearing. A contested case hearing shall be held on September 10, 2015, before the Board. The hearing shall begin at 8:30 a.m. and shall be located in the conference room at the Board office at 400 SW 8th Street, Suite C, Des Moines, Iowa.

2. Answer. Within twenty (20) days of the date you are served this Statement of Charges you are required by 653 IAC 24.2(5)(d) to file an Answer. In that Answer, you should state whether you will require a continuance of the date and time of the hearing.

3. Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge make initial rulings on pre-hearing matters, and be present to assist and advise the Board at hearing.

4. Prehearing Conference. A prehearing conference will be held by telephone on July 22, 2015, at 9:00 a.m., before an Administrative Law Judge from the Iowa Department of Inspections and Appeals (ALJ). Please contact Kent M. Nebel, J.D., Legal Director, Iowa Board of Medicine, at 515-281-7088 with the telephone number at which you or your legal counsel can be reached. Board rules on prehearing conferences may be found at 653 Iowa Administrative Code 25.15.

5. Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 653 IAC 25. At hearing, you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. If you need to request an alternative time or date for hearing, you must review the requirements in 653 IAC 25.16. The hearing may be open to the public or closed to the public at the discretion of the Respondent.

6. Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address: Julie Bussanmas, Assistant Attorney General, Iowa Attorney General's Office, 2nd Floor, Hoover State Office Building, Des Moines, Iowa 50319.

7. Communications. You may not contact Board members by phone, letter, facsimile, e-mail, or in person about this Notice of Hearing. Board members may only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You should direct any questions to Kent M. Nebel, J.D., the Board's Legal Director at 515-281-7088 or to Assistant Attorney General Julie Bussanmas 515-281-5637.

B. LEGAL AUTHORITY AND JURISDICTION

8. Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 148, and 272C.

9. Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148, and 272C and 653 IAC 25.

10. Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 653 IAC 25.20.

C. STATUTES AND RULES INVOLVED

COUNT I

11. **Professional Incompetency:** Respondent is charged with professional incompetency pursuant to Iowa Code sections 147.55(2), 148.6(2)(g) and (i), and 272C.10(2) and 653 IAC 23.1(2)(c), (d), (e), and (f), by demonstrating one or more of the following:

c. A substantial lack of knowledge or ability to discharge professional obligations within the scope of the physician's or surgeon's practice;

d. A substantial deviation from the standards of learning or skill ordinarily possessed and applied by other physicians or surgeons in the state of Iowa acting in the same or similar circumstances;

e. A failure by a physician or surgeon to exercise in a substantial respect that degree of care which is ordinarily exercised by the average physician or surgeon in the state of Iowa acting in the same or similar circumstances; or

f. A willful or repeated departure from, or the failure to conform to, the minimal standard of acceptable and prevailing practice of medicine and surgery in Iowa.

COUNT II

12. **Practice Harmful or Detrimental to the Public:** Respondent is charged pursuant to Iowa Code section 147.55(3) and 653 IAC 23.1(3) with engaging in practice harmful or detrimental to the public. Practice harmful or detrimental to the public includes, but is not limited to, the failure of a physician to possess or exercise that degree or skill, learning and care expected of a reasonable, prudent physician acting in the same or similar circumstances.

STATEMENT OF THE MATTERS ASSERTED

13. **Practice Setting:** Respondent is an Iowa-licensed physician who practices anatomic and clinical pathology in Marshalltown, Iowa.

14. **Professional Incompetency and/or Practice Harmful or Detrimental to the Public:** The Board alleges that Respondent demonstrated professional incompetency and/or practice harmful or detrimental to the public in violation the laws and rules governing the practice of medicine in Iowa when he failed to provide appropriate pathological services to multiple patients in Marshalltown, Iowa, including, but not limited to, the following:

A. **Patient #1 (Right breast core needle biopsy):** Respondent misdiagnosed invasive ductal carcinoma. Respondent inappropriately ordered multiple unnecessary immunohistochemical stains which were not indicated for a benign lesion.

B. **Patient #2 (Skin biopsies):** Respondent misdiagnosed malignant melanoma. Respondent inappropriately ordered a Melan-A stain which was not indicated for a benign lesion.

C. **Patient #3 (Axillary lymph nodes with prior diagnosis of malignant melanoma):** Respondent inappropriately ordered multiple unnecessary immunohistochemical stains which were not indicated given the obvious nature of the tumor cells in the lymph nodes.

D. **Patient #4 (Lymph node resection):** Respondent inappropriately ordered multiple unnecessary immunohistochemical stains which were not indicated given the obvious nature of the tumor cells in the lymph nodes.

E. **Patient #5 (Skin biopsy):** Respondent misdiagnosed an invasive malignant melanoma.

F. **Patient #6 (Skin of vulva):** Respondent misdiagnosed a lesion as "keratoacanthoma" when in fact the lesion was an invasive, well-differentiated, squamous cell carcinoma.

G. **Patient #7 (Vulvar skin biopsy):** Respondent misdiagnosed a lesion as "condyloma acuminatum" when in fact the lesion was a high-grade squamous intraepithelial lesion characterized by severe squamous dysplasia. Respondent inappropriately ordered multiple unnecessary immunohistochemical stains which were not indicated.

H. **Patient #8 (Vulvar skin biopsy):** Respondent misdiagnosed a lesion as "lichen sclerosus" when in fact the skin showed foamy histiocytes, chromic dermal inflammation, and hemosiderin deposition, with a subepidermal vesicle.

I. **Patient #9 (Vulvar skin biopsy):** Respondent misdiagnosed a lesion as "lichen sclerosus" when in fact the lesion was a benign squamous hyperkeratosis with dermal sclerosus and superficial bacterial colonies.

E. SETTLEMENT

15. Settlement. This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 653 IAC 25. If you are interested in pursuing settlement of this matter, please contact Kent M. Nebel, J.D., Legal Director at 515-281-7088.

F. PROBABLE CAUSE FINDING

16. On July 10, 2015, the Iowa Board of Medicine found probable cause to file this Statement of Charges.

Hamed H. Tewfik, M.D., Chairman
Iowa Board of Medicine
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Des Moines, Iowa 50309-4686