STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Susan E. Warwick, MD
Master Case No.: M2013-931
Document: Stipulation to Informal Disposition

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center
P.O. Box 47865
Olympia, WA 98504-7865
Phone: (360) 236-4700
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **SUSAN E. WARWICK, MD** License No. MD00029213 Respondent	**No. M2013-931** **STIPULATION TO INFORMAL DISPOSITION**

Pursuant to the Uniform Disciplinary Act, Chapter 18.130 RCW, the Medical Quality Assurance Commission (Commission) issued a Statement of Allegations and Summary of Evidence (Statement of Allegations) alleging the conduct described below. Respondent does not admit any of the allegations. This Stipulation to Informal Disposition (Stipulation) is not formal disciplinary action and shall not be construed as a finding of unprofessional conduct or inability to practice.

1. ALLEGATIONS

1.1 On November 20, 1991, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent is board-certified in obstetrics and gynecology. Respondent's license is currently active.

1.2 Between August 2011 and May of 2012, Respondent had two surgical cases (Patients A and B) in which a foreign object was unintentionally left inside the patient following surgery. In addition to the issues regarding two retained foreign bodies, the Commission also had concerns regarding Respondent's laparoscopic approach in the case of Patient B.

Patient A

1.3 On August 18, 2011, Respondent performed a Cesarean Section (C-section) and delivered a healthy baby to Patient A. Patient A was, at that time, a 21-year-old female, who had failed to progress to delivery after labor had been medically induced.

1.4 Prior to closure of Patient A's abdomen to conclude the C-section, Respondent and the surgical team recorded correct sponge, needle, and instrument counts.

ORIGINAL

1.5 In December of 2011, Patient A made multiple visits to the emergency room due to unresolved nausea and vomiting. A CT scan on December 21, 2011 revealed a partial small bowel obstruction with a foreign body. On December 23, 2011, a surgeon performed a laparotomy with adhesiolysis, drainage of an intra-abdominal abscess, repair of Patient A's small intestine, and retrieval of a laparotomy sponge.

1.6 Immediately after learning of the unintended retained sponge, Respondent contacted Patient A and apologized personally and on behalf of the surgical team. Respondent has made two changes to her surgical practice, intended to minimize the risk of recurrence of this error. First, in addition to following the existing sponge count protocol, Respondent has surgical team members record any use of a sponge or towel in the abdomen on a whiteboard visible to the surgical team. Second, Respondent now uses a special C-section retractor designed to increase visibility and decrease the need for surgical sponges.

Patient B

1.7 Patient B was a 43-year-old morbidly obese female with a history of abdominal surgery, that included a Cesarean Section and tubal ligation in 2005, a laparoscopic cholecystectomy in December 2005, and laparoscopic resection of endometriosis in November 2008. Following the November 2008 procedure to remove endometriosis, performed by another surgeon, Patient B continued to experience pain, heavy bleeding with menses, and other symptoms. Patient B was informed of treatment options and chose to undergo total laparoscopic hysterectomy.

1.8 On May 22, 2012, Respondent began performing a laparoscopic total hysterectomy on Patient B. Before beginning the laparoscopic surgery, Respondent used a RUMI (brand name) uterine manipulator to obtain better visualization and access during the laparoscopic procedure. A uterine tip at the end of the RUMI device was advanced through the cervical canal, into the uterus, and secured into position with a balloon inflated with saline. An attachment called a Koh cup was advanced along the RUMI device, into the vagina, and was seated at the opening of the cervix.

1.9 Respondent then began the laparoscopic surgery. She made an incision at the umbilicus, and after lifting the abdomen in attempt to separate any potential adhesions from the abdominal wall, she placed a blunt tissue dissecting trocar using a laparoscope for visualization. It immediately became apparent that the laparoscope

was in the lumen of the small bowel. Respondent and the assisting surgeon decided to convert the procedure to an open procedure, so that they could repair the perforation in the small bowel. Respondent removed the RUMI device, but did not remove the Koh cup. The assisting surgeon repaired the small bowel, and Respondent completed the hysterectomy. Shortly following Respondent's completion of the hysterectomy, the patient began experiencing declining oxygen saturation, requiring attention from multiple anesthesiologists. After the procedure was completed, Patient B was immediately taken for CT imaging, where it was determined that she did not have a pulmonary embolism. Patient A was subsequently taken to the Critical Care Unit (CCU) by order of the anesthesiologist for treatment of her continued oxygen saturation issues, which resolved the following day without discover of the etiology. The Koh cup remained in Patient B.

1.10 In the month following surgery, Patient B experienced a foul smelling vaginal discharge, and abdominal pain that may have been associated with other medical issues. On June 25, 2012, Patient B's regular gynecologist did a vaginal exam and discovered the unintentionally retained Koh cup. The Koh cup was removed two days later, with Patient B under general anesthesia.

1.11 In response to this event, Respondent now uses a RUMI device that does not separate from the vaginal cup. Respondent has also responded to this event by requiring, as a matter of protocol, that the Koh cup be accounted for by including it in the surgical checklist.

1.12 In addition to the retained foreign body issue, it is the Commission's position that because of Patient B's history of abdominal surgery, with the attendant likelihood of abdominal adhesions, Respondent did not appropriately visualize the peritoneum for adhesions to the bowel before inserting the trocar and laparoscope. Respondent should have either correctly performed the direct entry visualization technique that she used, or alternatively used an open laparoscopic approach (Hasson technique) to avoid the bowel injury that occurred. Although bowel injury during the course of a total laparoscopic hysterectomy is a known complication, this injury might have been avoided in this case with the correct performance of an appropriate approach.

2. STIPULATION

2.1 The Commission alleges that the conduct described above, if proven, would constitute a violation of RCW 18.130.180(4).

2.2 The parties wish to resolve this matter by means of a Stipulation to Informal Disposition (Stipulation) pursuant to RCW 18.130.172(1).

2.3 Respondent agrees to be bound by the terms and conditions of this Stipulation.

2.4 This Stipulation is of no force and effect and is not binding on the parties unless and until it is accepted by the Commission.

2.5 If the Commission accepts the Stipulation it will be reported to the Health Integrity and Protection Databank (HIPDB)(45 CFR Part 61), the Federation of State Medical Board's Physician Data Center, and elsewhere as required by law. HIPDB will report this Stipulation to the National Practitioner Data Bank (45 CFR Part 60).

2.6 The Statement of Allegations and this Stipulation are public documents. They will be placed on the Department of Health web site, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). They are subject to disclosure under the Public Records Act, Chapter 42.56 RCW, and shall remain part of Respondent's file according to the state's records retention law and cannot be expunged.

2.7 The Commission agrees to forego further disciplinary proceedings concerning the allegations.

2.8 Respondent agrees to successfully complete the terms and conditions of this informal disposition.

2.9 A violation of the provisions of Section 3 of this Stipulation, if proved, would constitute grounds for discipline under RCW 18.130.180 and the imposition of sanctions under RCW 18.130.160.

3. INFORMAL DISPOSITION

The Commission and Respondent stipulate to the following terms.

3.1 **Protocol.** Respondent will work with any facility at which she performs surgery to develop a written protocol designed to prevent the unintended retention of foreign bodies. If such a protocol already exists at the facilities at which she performs

surgery, Respondent will provide the Commission with a copy of the existing protocol. Respondent will submit the protocol to the Commission, at the address below, within sixty (60) days of the effective date of this Stipulation. In order to satisfy this provision, the protocol must incorporate and be consistent with the recommendations in this area found in the opinion of the Committee on Patient Safety and Quality Improvement of the Amercian College of Obstetrics and Gynecology (ACOG). Respondent will immediately implement, or continue to implement, this protocol in her practice.

3.2 **Root/Cause Analysis of Surgical Sponge Case.** Within sixty (60) days of the effective date of this Stipulation, Respondent will submit to the Commission a paper of at least one thousand words, with annotated bibliography, in which she provides a root cause analysis of the factors leading to the retained surgical sponge in this case. Respondent will also describe the changes she has made in her practice to address the root cause of the error in this case, and how they will help to prevent recurrence. The paper must be approved by the Commission. Respondent will submit the protocol and paper to:

Compliance Officer
Department of Health, Medical Quality Assurance Commission
P.O. Box 47866
Olympia, Washington 98504-7866.

3.3 **Paper.** Within sixty (60) days of the effective date of this Stipulation, Respondent will submit to the Commission a paper of at least one thousand words, with annotated bibliography, containing a discussion regarding the need for visualization of the lining of the peritoneum and the correct performance of an appropriate laparoscopic approach for patients with a history of abdominal surgery. The paper must be approved by the Commission or its designee. Respondent will submit the paper to the address above.

3.4 **Presentation.** Within six (6) months of the effective date of this Stipulation, Respondent will make a presentation regarding these two surgical cases, and the above papers and protocol, to a peer group at a facility where Respondent performs surgery, or to another group that will benefit from education on these issues. Respondent will provide the Commission with written notification of the date of the presentation, and a description of the audience and subject matter discussed.

3.5 **Obey Laws.** Respondent must obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

3.6 **Costs.** Respondent must assume all costs that she incurs in complying with this Stipulation.

3.7 **Violations.** If Respondent violates any provision of this Stipulation in any respect, the Commission may initiate further action against Respondent's license.

3.8 **Change of Address.** Respondent must inform the Commission and the Adjudicative Clerk Office in writing, of changes in her residential and/or business address within thirty (30) days of such change.

3.9 **Termination.** Upon completion of the requirements in paragraphs 3.1 through 3.4 above, Respondent may petition the Commission in writing for termination of this Stipulation. Upon a written petition to terminate, Respondent will appear in person before the Commission, at a date and location designated by the Commission. Respondent will answer any questions from the Commission regarding lessons learned from these cases, regarding her compliance with this Stipulation, or regarding her practice. If the Commission determines that Respondent has satisfied the requirements of this Stipulation, the Commission will terminate this Stipulation effective upon the date of the decision, and will memorialize the decision in a letter to Respondent.

3.10 **Effective Date.** The effective date of this Stipulation to Informal Disposition is the date the Adjudicative Clerk Office places the signed Stipulation into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Stipulation.

4. COMPLIANCE WITH SANCTION RULES

4.1 The Commission applies WAC 246-16-800, *et seq.* (the "Sanction Rules"), to determine appropriate terms for stipulations to informal disposition. The Sanction Rules identify several categories of misconduct and create a schedule of sanctions for each category using a tier system. This case involves two separate incidents of alleged misconduct, both of which would fit within the "Practice Below Standard of Care" schedule, WAC 246-16-810. The Sanction Rules specify that "when different acts of unprofessional conduct fall in the same sanction schedule, the highest sanction [associated with any of the acts of unprofessional conduct] is imposed and the

[remaining] acts of unprofessional conduct are considered aggravating factors." WAC 246-16-800(3)(a)(ii). This provision should be interpreted to require imposition of the highest of sanction ranges associated with the conduct, and not the highest or most severe sanction within the range. The latter interpretation would render superfluous the language about consideration of other acts as aggravating factors.

4.2 In this case, both of the acts of alleged unprofessional conduct involve the unintentional retention of foreign bodies following surgery, and both fall clearly within Tier B of the "Practice Below Standard of Care" schedule, WAC 246-16-810. Tier B applies to cases where substandard practices result in moderate patient harm or the risk of moderate to severe harm. In case number 2013-4762, the retained sponge caused Patient A moderate harm in the form of discomfort associated with the retained body and the subsequent medical developments. The retained sponge also created the risk of moderate to severe harm associated with the additional surgery and anesthesia. Patient A recovered well and does not appear to have suffered permanent damage. Tier B therefore applies to case number 2013-4762. In case number 2014-6299, the vaginal cup that Respondent unintentionally left in Patient B's vagina did appear to have caused her moderate harm in the form of the foul smelling vaginal discharge, and possibly some associated discomfort. The retained cup also created the risk of moderate to severe harm associated with the general anesthesia required for its removal. It is the Commission's position that Respondent's performance of a direct entry visualization approach, without sufficiently visualizing the lining of the peritoneum for adhesions prior to entry, also caused moderate harm related to the bowel perforation and created the risk of moderate to severe harm. Tier B therefore applies to case number 2014-6299 as well.

4.3 Tier B requires the imposition of terms ranging from two years of oversight to five years of oversight, unless revocation. However, under WAC 246-16-800(3)(d)(iii), the Commission may deviate from the range based upon mitigating and aggravating factors, if the Commission identifies the deviation and explains the reasons for the deviation. In this case, the terms of the Stipulation may be accomplished well before the minimum two year period of Tier B. This Stipulation is therefore a deviation. This deviation is justified by the weight of the following mitigating factors over the aggravating factors:

Mitigating Factors

A. Regarding Patient A, Respondent was ensured by surgical team members that the sponge count was correct prior to closing Patient A's abdomen.

B. Respondent acknowledged the error and immediately apologized to Patient A on behalf of Respondent and the surgical team.

C. Respondent acknowledged the error regarding the retained vaginal cup, and apologized to Patient B at her earliest opportunity.

D. As described in the allegations above, Respondent initiated changes to her practice designed to prevent recurrence of the errors that occurred in both cases.

E. It is the Commission's conclusion that the issue's raised regarding Respondent's care in these two cases were promptly acknowledged and addressed by Respondent, are further addressed by this Stipulation, and do not require a specified period of oversight of this physician who has been licensed in Washington for more than 23 years.

Aggravating Factor

A. Respondent was previously subject to a stipulation to informal disposition, entered July 11, 2002, regarding an unrelated subject. Respondent fully complied with that stipulation and was released in September of 2003.

B. This Stipulation involves alleged substandard care for two patients.

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5. RESPONDENT'S ACCEPTANCE

I, SUSAN E. WARWICK, MD, Respondent, certify that I have read this Stipulation to Informal Disposition in its entirety; that my counsel of record, PATRICK C. SHELDON, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Commission without my appearance. If the Commission accepts the Stipulation to Informal Disposition, I understand that I will receive a signed copy.

SUSAN E. WARWICK, MD
RESPONDENT

4/22/15
DATE

PATRICK C. SHELDON, WSBA #11398
ATTORNEY FOR RESPONDENT

April 26 2015
DATE

6. COMMISSION'S ACCEPTANCE

The Commission accepts this Stipulation to Informal Disposition. All parties shall be bound by its terms and conditions.

DATED: 14 May, 2015.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

W E Gottstein MD
PANEL CHAIR

PRESENTED BY:

JAMES P. MCLAUGHLIN, WSBA #27349
DEPARTMENT OF HEALTH STAFF ATTORNEY