

Laparoscopic Cholecystectomy Exception Requirements

The facility must file for exception with the Department pursuant to 28 Pa. Code § 51.33. *See*, Agreement Para. 13. In addition to any other requirements set forth in the Department's regulations, the new or supplemental application must include the following:

- Written agreement to comply with the patient selection and minimum patient exclusion criteria listed in Paragraphs 13.a.i.A (appropriate patients) and 13.a.i.B (exclusion criteria) of the Agreement.
- Written confirmation of having met the requirements listed in Paragraphs 13.b.i, 13.b.ii and 13.b.iii, pertaining to credentialing of physicians, including documentation demonstrating those requirements have been met by physicians the ASF seeks to credential.
- Designation of the physicians for whom clinical privilege to perform laparoscopic cholecystectomies is sought, including written agreement to re-credential physicians to perform laparoscopic cholecystectomies at least every two years.
- A patient consent form informing the patient of: reasonably foreseeable risks and complications that may arise during a laparoscopic cholecystectomy, including those that may require conversion to an open cholecystectomy or hospitalization; the ASF's arrangements for a patient to be transferred to a hospital, if required; the availability of a hospital as the site for the laparoscopic surgery; and, the comparative risks and benefits associated with performing the procedure in the ASF or in a hospital.
- The ASF's procedures, as per 28 Pa. Code § 555.23(d) and (e), for ensuring that a patient who needs to be transferred to a hospital following a laparoscopic cholecystectomy, or a laparoscopic cholecystectomy converted to open cholecystectomy, will be transferred by qualified personnel and transportation equipment, and that patient records related to the procedure performed will be sent with the patient to the hospital.
- Written agreement to promptly file reports as may be required under Section 6 of the Health Care Cost Containment Act, 35 P.S. § 449.6; the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. §§ 1303.301 – 1303.314; and, Department regulations.
- Written agreement to initiate peer review as provided for in Paragraph 13.a.vii of the Agreement, within 30 days of a laparoscopic cholecystectomy procedure that results in: an unintended injury to the aorta, vena cava, portal vein, or hepatic artery, or other unintended non-de minimis vascular injury; an injury to the common bile duct; or, a non-de minimis injury to the intestines or other organs.

Please review 28 Pa. Code §§ 51.31 – 51.34 and the enclosed Agreement carefully for a complete explanation of the procedure for requesting and receiving an exception pursuant to the terms of the Agreement. If you have any questions, please contact the Department at 717-783-8980.

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

THE PENNSYLVANIA MEDICAL SOCIETY;
THE FEDERATED AMBULATORY SURGERY
ASSOCIATION; THE PENNSYLVANIA
AMBULATORY SURGERY ASSOCIATION;
LEADER SURGICAL CENTER; IGNACIO PRATS,
MD; and VASUDEVAN TIRUCHEVELVAM, MD
Petitioners,

v.

COMMONWEALTH OF PENNSYLVANIA,
DEPARTMENT OF HEALTH
Respondents

No 361 MD 2005

AGREEMENT

Background

1. Petitioners the Pennsylvania Medical Society, the Federated Ambulatory Surgery Association (“FASA”), the Pennsylvania Ambulatory Surgery Association (“PASA”), Leader Surgical Center, Ignacio Prats, M.D., Vasudevan Tiruchelvam, M.D. (jointly referred to as “Petitioners”) have filed a Petition for Review and a Motion for Special Relief in the Nature of a Preliminary Injunction against the Commonwealth of Pennsylvania, Department of Health (“Respondent”). The Petition for Review asserted that the Medical Society, FASA, and PASA brought this action on behalf of their members. The Petition and Motion challenge Respondent’s actions in regulating what laparoscopic procedures ambulatory surgical facilities (“ASFs”) may provide and, more specifically, Respondent’s action in denying the exception request of Leader Surgical Center to provide laparoscopic cholecystectomies.

2. Respondent has filed Preliminary Objections to the Petition for Review seeking to dismiss the Petition, asserting lack of ripeness and the failure of Petitioners to exhaust administrative remedies.

3. The Parties have engaged in discovery and presented evidence at the preliminary injunction hearing on the experience required by a surgeon to perform laparoscopic cholecystectomies without supervision, the medical risks involved in performing laparoscopic cholecystectomies, the possibility of needing to convert to an open cholecystectomy when a laparoscopic cholecystectomy is attempted, and the possibility of the need to hospitalize a patient when a laparoscopic cholecystectomy is performed in a hospital or an ASF setting.

4. Argument on Respondent's Preliminary Objections and a hearing on Petitioners' Application for Special Relief in the Nature of a Preliminary Injunction were held on August 16, 2005, in the Commonwealth Court and decisions on the Preliminary Objections and Application for Special Relief are currently pending.

5. The depositions and hearing record reflect that laparoscopic procedures are not risk-free. Petitioners construe the deposition and hearing record to also reflect that qualified surgeons, including general surgeons, exercising proper patient selection criteria, can perform laparoscopic cholecystectomies safely in an ASF. The depositions and hearing record reflect that there are a substantial number of articles in professional journals addressing the safety of performing laparoscopic cholecystectomies in an outpatient setting, including in an ASF, but no articles comparing outcomes of similarly selected patients who receive laparoscopic cholecystectomies in hospitals versus ASFs. The articles and testimony reflect that when laparoscopic cholecystectomies are performed by highly qualified general surgeons using conservative patient selection criteria a low percentage of cases will convert from a laparoscopic cholecystectomy to an open cholecystectomy and that hospital admissions will be necessary in these cases and, for other reasons, in a low percentage of additional cases.

6. Respondent's ASF regulations do not prescribe minimum qualifications needed by surgeons to perform surgical procedures in an ASF and do not prescribe patient selection criteria ASFs

should employ to determine which patients should receive a surgical procedure in a hospital rather than in an ASF.

7. Respondent's regulations provide, at 28 Pa. Code § 551.21(d)(2), that surgical procedures of a type that require a "major" invasion of a body cavity are prohibited in an ASF.

8. Respondent and Petitioners agree that the performance of a laparoscopic cholecystectomy is a surgical procedure that requires an invasion of a body cavity, the peritoneal cavity. Respondent considers a laparoscopic procedure that penetrates into the peritoneal cavity to constitute a major invasion of a body cavity and Petitioners consider a laparoscopic procedure that penetrates into the peritoneal cavity to constitute a minor invasion of a body cavity. Respondent had not communicated its interpretation to ASFs until December of 2004. Some ASFs had been providing laparoscopic procedures for a number of years prior to that announcement.

9. Respondent has the authority under 28 Pa. Code § 51.31 to grant to ASFs exceptions to Respondent's regulations, including those regulations that prohibit an ASF from providing certain surgical procedures. Respondent may impose reasonable conditions in granting such exceptions.

10. Respondent has initiated a review of its regulations applicable to acute care facilities, including ASFs, which will involve proposing and adopting revisions to Respondent's ASF regulations, including those applicable to the performance of surgical procedures in an ASF, if needed as determined by Respondent.

AGREEMENT

Based on the foregoing, the Petitioners and Respondent, in consideration of the mutual promises set forth below and intending to be bound thereby, agree as follows:

11. Petitioners will not contest Respondent's interpretation that a laparoscopic surgical procedure that penetrates the peritoneal cavity is a major invasion of a body cavity, as that term is used

in 28 Pa. Code § 551.21(d)(2), in any action Petitioners may file for the purpose of enabling an ASF to provide a laparoscopic procedure.

12. If Respondent grants exceptions to its regulations that otherwise prohibit certain surgical procedures from being provided by an ASF, for those surgical procedures that have been approved by the Centers for Medicare and Medicaid Services (CMS) for reimbursement in an ASF for Medicare beneficiaries, Petitioners will not use that grant of an exception in any manner to challenge the Respondent's denial of an exception application for a surgical procedure not on the CMS list.

13. Respondent will, by individual letters, issued promptly upon compliance with the terms of this Agreement, grant the exceptions to perform laparoscopic cholecystectomies previously requested by Leader Surgical Center and other ASFs, and grant in the future other exception requests by ASFs to perform laparoscopic cholecystectomies that are otherwise in compliance with Respondent's ASF regulations, subject to the following and their agreement to an exception under such terms:

a. The ASF must include in its application for an exception or supplement its application for an exception by:

i. Agreeing to comply with the following patient selection and minimum patient exclusion criteria:

A. Appropriate patients if no exclusion criteria present:

1. History of gallstones without acute cholecystitis
2. Biliary dyskensia
3. Gallbladder polyp

B. Exclusion criteria:

1. Classification PS-III, if the systemic disturbance resulting in the classification is not controlled at an acceptable function or level

2. 65 years of age or older
- 3 300 pounds or heavier, or otherwise morbidly obese
4. Patient does not have necessary knowledge and willingness to follow postoperative instructions or no responsible adult will be with the patient for the first 24 hours following the surgery
5. Known common bile duct stones
6. History of pancreatitis
7. History of clinically-significant pulmonary disease
8. History of unstable heart disease
9. History of uncontrolled diabetes
10. Chronic renal failure
11. Active myasthenia gravis
12. History of recent CVA
13. Previous upper abdominal surgery in the same quadrant
14. History of bleeding or clotting abnormalities
15. Sleep apnea, unless the anesthesiologist or CRNA specifically determines that the administration of anesthesia to the patient and discharge to home is safe under the presenting circumstances.

ii. Confirming that it has met the requirements of subparagraph b below, which pertain to credentialing physicians to perform laparoscopic cholecystectomies.

iii. Designating the physicians for whom the clinical privilege to perform laparoscopic cholecystectomies at the ASF is sought, and agreeing to re-credential each such physician at least every two years.

iv. Providing a patient consent form that sets forth reasonably foreseeable risks and complications that may arise during a laparoscopic cholecystectomy, including those that may require a conversion to an open cholecystectomy or hospitalization; the ASF's

arrangements for a patient to be transferred to a hospital, if required; the availability of a hospital as the site for the surgery; and the comparative risks and benefits associated with performing the procedure in the ASF or in a hospital.

v. Setting forth its procedures, as per 28 Pa. Code § 555.23(d) and (e), for ensuring that a patient who needs to be transferred to a hospital following a laparoscopic cholecystectomy or a laparoscopic cholecystectomy converted to open cholecystectomy will be transferred by qualified personnel and transportation equipment, and that patient records related to the procedure performed will be sent with the patient to the hospital.

vi. Agreeing to promptly file reports as may be required under Section 6 of the Health Care Cost Containment Act, 35 P.S. § 449.6; the Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. §§ 1303.301 – 1303.314; and as required by Respondent's regulations.

vii. Agreeing to initiate peer review within 30 days of a laparoscopic cholecystectomy procedure that results in: an unintended injury to the aorta, vena cava, portal vein, or hepatic artery, or other unintended non-de minimis vascular injury; an injury to the common bile duct; or a non-de minimis injury to the intestines or other organs (an example of a de minimis injury is a superficial cautery burn). The review shall be conducted by a group of peers that includes at least one physician who is not an owner of the ASF and who does not perform surgical procedures or other services at the ASF, with documented review and determination available to Respondent upon request.

b. The ASF must document the following in its credentialing records for each physician for whom the clinical privilege to perform laparoscopic cholecystectomies at the ASF is sought:

i. That the physician has performed at least 50 laparoscopic cholecystectomies in any practice setting, at least a total of 20 unsupervised laparoscopic cholecystectomies in all practice settings during each of the two prior 12-month periods, and at least 5 unsupervised open cholecystectomies. For each credentialing of a physician, there shall be documentation in the credentialing file that the ASF has considered the clinical record of the physician at all other sites where the physician performed laparoscopic cholecystectomies during the credentialing period. The documentation shall include: the name of the facility, the physician's privileges and staff status, the number of laparoscopic cholecystectomies the physician performed, the number of those laparoscopic cholecystectomies referred for peer review, the outcomes of the reviews, and corrective actions.

ii. That, based on its own records and information made available to it by other facilities, in no more than 2% or more than one qualifying event, whichever is a greater percentage, of laparoscopic cholecystectomies the physician performed during the immediately preceding twelve months, at all sites where the physician practices, collectively any of the following occurred: an unintended injury to the aorta, vena cava, portal vein, or hepatic artery, or other unintended non-de minimis vascular injury; an injury to the common bile duct; or a non-de minimis injury to the intestines or other organs. Any event otherwise fitting within those categories shall be excluded if an applicable peer review found that the physician followed appropriate standards of care in the procedure at issue.

iii. That the physician has admitting privileges at a hospital in close proximity to the ASF which has emergency and surgical services available, or has made arrangements

with a physician who has those privileges, to ensure the admission of a patient upon whom a cholecystectomy was performed at the ASF who requires hospitalization.

14. An ASF granted an exception pursuant to Paragraph 13 may grant privileges for other physicians to perform laparoscopic cholecystectomies at the ASF who satisfy the criteria established by Paragraph 13.b.i, ii and iii within 10 days after identifying the physician in writing to the appropriate Respondent field office and confirming that the ASF has satisfied its responsibilities under 13.b.i, ii and iii. Respondent may review the credentialing information at the annual survey or, on request, at an earlier date.

15. Respondent may revoke an exception granted pursuant to this Agreement if it determines that the ASF has falsified its application for the exception or any of its records pertinent to the continuation of an exception, is not in compliance with the conditions of an exception granted pursuant to this Agreement, or has failed to comply with applicable statutes or regulations materially relevant to the performance of laparoscopic cholecystectomies. The revocation shall be effective immediately, with the ASF being afforded the opportunity for a hearing before the Secretary of Health or an agency head designated by the Secretary within 30 days after receiving notice of a revocation and for issuance of an adjudication within 60 days after the hearing (which shall include a 15-day briefing period if requested by the agency head or a party) has concluded. Unless the ASF agrees to a longer period of time or its actions prevent compliance, compliance with those time periods is a condition of the continued revocation of the exception, pending final action in the hearing.

16. The ASF shall immediately terminate a physician's privilege to perform laparoscopic cholecystectomies at the ASF when it determines that the physician has performed collectively at all sites more than 2%, or more than one qualifying event, whichever is a greater percentage, of laparoscopic cholecystectomies during the immediately preceding twelve months in which collectively

any of the following occurred: an unintended injury to the aorta, vena cava, portal vein, or hepatic artery or other unintended non-de minimis vascular injury; an injury to the common bile duct; or a non-de minimis injury to the intestines or other organs. Any event otherwise fitting within those categories shall be excluded if peer review conducted as per Paragraph 13.a.vii or, if the event occurred at a hospital, conducted as per the hospital's peer review procedures, found that the physician followed appropriate standards of care in the procedure at issue. The ASF shall promptly notify Respondent of its action. The ASF may apply to Respondent to again include that physician in the exception when it documents that the physician has performed at all sites 2% or less laparoscopic cholecystectomies, or more than one qualifying event, whichever is a greater percentage, in which the specified problems occurred during the immediately preceding twelve months or peer review (as per Paragraph 13) concludes that professional error did not cause a sufficient number of the specified problems so as to reduce the physician's total error rate when performing laparoscopic cholecystectomies to 2% or less (or one or less, whichever is a greater percentage). The ASF shall also immediately terminate a physician's privilege to perform laparoscopic cholecystectomies at the ASF upon receiving documented evidence that the physician materially falsified the physician's credentials or patient records or that those records were otherwise materially falsified.

17. The ASF's exception shall immediately terminate, without hearing, if during the immediately preceding twelve months there were more than 2%, or more than one event, whichever is a greater percentage of laparoscopic cholecystectomies at the ASF in which collectively any of the following occurred: an unintended injury to the aorta, vena cava, portal vein, or hepatic artery; an injury to the common bile duct; or a non-de minimis injury to the intestines or other organs. Any event otherwise fitting within those categories shall be excluded if peer review conducted as per

Paragraph 13.a.vii found that the physician followed appropriate standards of care in the procedure at issue.

18. In reviewing future exception requests of ASFs under 28 Pa. Code § 51.31 for exceptions to perform laparoscopic procedures other than cholecystectomies, Respondent shall consider, among other pertinent matters, if presented: (1) patient selection criteria, analogous to Paragraph 13.a.i, appropriate to the condition and procedure at issue; (2) the qualifications and experience of surgeons proposed to perform the procedure; (3) the reasonably expected risks and complications of the procedure and the manner in which they will be addressed at the ASF, including the medications, equipment, and personnel needed to do so, and/or by transfer to a hospital within the time needed; and (4) professional literature discussing the safety of performing the procedure in a freestanding setting, and/or on an out-patient basis. Respondent, in reviewing exception requests, will also consider whether granting the exception will improve the capacity of the health care facility to deliver higher quality care and services and/or to operate more efficiently without compromising patient or resident care, and will consider, as part of that review, whether the policy and objectives as per 28 Pa. Code § 51.32 are otherwise met.

19. Exceptions, including any extension of the exception or of an exception granted in the future, are subject to subsequent actions of the General Assembly or new DOH regulations that substantively change the “major invasion of body cavity” standard. If there is a material change in the statutes or regulations pertinent to an ASF providing laparoscopic procedures, nothing in this agreement shall prevent the holder of an exception from pursuing legal action to allow it to provide the laparoscopic procedure without complying with the terms of the exception or limit the issues that can be raised in any such action. If the subsequent changes in the applicable statutes or regulations eliminate the need for an exception, as agreed upon by the Parties, the exception shall terminate.

20. If any of the parties believe that any of the criteria in Paragraph 13.a.i. are unnecessary to accomplish the purposes of this Agreement or that additional criteria are necessary to do so, they shall advise the other parties to this Agreement and provide appropriate support for the proposed revision. The parties shall negotiate in good faith as to such revisions. If the parties are unable to reach agreement on revisions, the party proposing the revision may, after reasonable efforts have been made, seek to revise the agreement in an action filed in an appropriate forum.

21. In the event the Medicare program should authorize payment for laparoscopic cholecystectomies at ASFs, Respondent will, in good faith, consider whether it is appropriate to eliminate or raise the age exclusion criterion in Paragraph 13.a.i.B.2.

22. Petitioners will, at their expense, discontinue this action and not seek to recover any costs from Respondent.

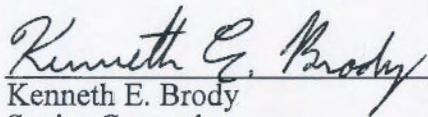
23. This Agreement shall bind and inure to the benefit of the Parties hereto provided, however, that any grant of an exception shall be limited to the surgeon(s) identified in the exception request and no assignment shall authorize additional surgeons to perform the surgery or to do so at a different facility than specified in the exception. Any changes in ownership of an ASF shall be dealt with in accordance with 28 Pa. Code § 51.4 and any other applicable regulation of Respondent.

24. This Agreement represents the entire understanding and agreement between the Parties with respect to the subject matter of this Agreement, and supersedes all prior written and oral negotiations, agreements, contracts, representations, understandings and commitments with respect thereto.

25. Each of the signatories to this Agreement represents that he or she has the full power and authority (and that all necessary approvals or consents have been obtained) to enter into this Agreement, and to bind his or her principal, to perform the obligations set forth herein.

26. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original as against any signatory appearing thereon, and all of which together will constitute one and the same instrument.

27. This Agreement shall be governed, interpreted and enforced pursuant to the laws of the Commonwealth of Pennsylvania without regard to its conflict of laws rules.



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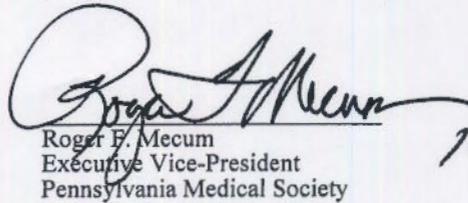
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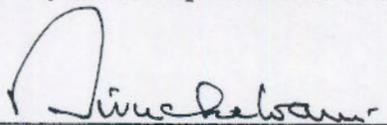
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For the Pennsylvania Medical Society

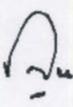
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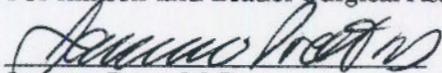
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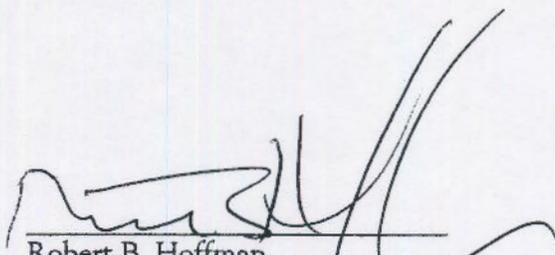
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