

March 7, 2005

(717) 783-1078

Dear Ambulatory Surgical Facility Provider:

This letter addresses the Department of Health's (DoH) plans with respect to ambulatory surgical facilities (ASF) that either are performing or that want to perform surgical procedures beyond those that the DoH believes to be permitted under its regulations. Among other things, this letter explains an expedited exceptions process that the DoH has initiated for ASFs that want to perform those surgical procedures that are prohibited under the DoH's interpretation of its regulations, but that appear on the Medicare Program's "Ambulatory Surgical Center List of Covered Procedures" (Medicare List). This letter also explains the regular exceptions process that is available to providers who want to perform procedures beyond those currently on the Medicare List.

The DoH's existing ASF regulations, found at 28 Pa. Code § 551.21, set forth limitations on the kinds of surgical procedures that may be performed in an ASF. Surgical procedures are limited to those that do not exceed a total of four (4) hours of operating time and four (4) hours of directly supervised recovery time. General anesthesia, if used, may not exceed four (4) hours. In addition, the surgical procedures may not be of a type that:

- (1) Are associated with the risk of extensive blood loss.
- (2) Require major or prolonged invasion of body cavities.
- (3) Directly involve major blood vessels.
- (4) Are emergency or life threatening in nature unless no hospital is available for the procedure and the need for surgery could not have been anticipated.

During a regular inspection last year, the Office of Quality Assurance, Division of Acute and Ambulatory Care, cited an ASF that DoH believed was violating these regulations by performing laparoscopic cholecystectomies. The DoH believes this procedure is a major invasion of a body cavity, as are most procedures that penetrate the peritoneal membrane. Following its notification to providers that procedures such as laparoscopic cholecystectomies were not permitted in the ASF setting, some ASFs objected that some of these procedures were safe and should be allowed.

In response to these providers' concerns, the DoH proceeded to meet on a number of occasions with the Pennsylvania Medical Society, the Federated Ambulatory Surgery Association and the Pennsylvania Ambulatory Surgery Association. We reviewed the applicable literature made available to us by provider organizations and through our own research. We worked with the Pennsylvania Health Care Cost Containment Council to collect available data into formats that would be helpful. We found that some ASFs were performing procedures that the DoH believes to be prohibited under its regulations. We also surveyed other states and found that Pennsylvania is more restrictive than other states, which tend to rely upon Medicare to control the types of procedures performed in ASFs.

The DoH agrees that providers have raised valid points and proposes to convene a group of stakeholders to review the current regulation and determine what changes are appropriate. This process, however, will take time and some providers that have been performing these procedures on a routine basis need more immediate relief. Therefore, the DoH has implemented the following two-pronged exceptions process.

In addition to the procedures allowed under the state regulations, the DoH has determined that ASFs should have the opportunity to perform procedures that are on the Medicare List since these procedures have been reviewed and approved by the federal government on a procedure-by-procedure basis for their safety in a freestanding ambulatory setting. This list is developed under § 1833(i)(1) of the Social Security Act, which requires CMS to specify surgical procedures that can be safely performed in a freestanding ambulatory surgical setting. The Medicare List is published in the Federal Register as an addendum to 42 CFR Part 416.

Licensed ASFs that want to perform those procedures that DoH believes are not currently permitted under its regulations, but that do appear on the Medicare List, may file an expedited exception request with the DoH using the attached form. Facilities must specify by HCPCS code and description which of those procedures from the Medicare List they wish to perform. Facilities must agree that the performance of those procedures for which they obtain an exception must comply with Medicare standards that limit surgical procedures to 90 minutes of operating time, four (4) hours of recovery time, and 90 minutes anesthesia time where general anesthesia is used. Facilities are also required to report all transfers to hospitals and other reportable events under the PA-PSRS reporting system established under the provisions of the MCARE Act.

Those facilities that want to perform procedures that DoH believes are prohibited under its regulations and that do not currently appear on the Medicare List, may apply for a regular exception under 28 Pa. Code §§ 51.31 - 51.34. The facility should address the criteria set forth in the exceptions regulations and include data to support the facility's safety record, the experience levels of its surgeons performing the requested procedures, quality assurance and improvement systems in place to track and address safety issues, patient selection criteria, transfers and complications resulting from the surgeries, policies and procedures to handle emergency situations and whether or not the regulation or the DoH's enforcement of the regulation has created an unreasonable hardship on the provider.

In summary,

1. If you believe that you have been performing (or that you intend in the future to perform) only those procedures that are allowed under the Pennsylvania Department of Health ASF regulation, no further action is required.
2. If, in addition to the above procedures, you want to perform any procedure on the Federal Medicare list, please complete attachment # 2 and send it to the DoH. For the fastest response, e-mail the electronic request to [ra-paexcept@state.pa.us](mailto:ra-paexcept@state.pa.us) and then mail us the signed hard copy. Please do not modify the form and be sure to identify for us the specific procedures on the Medicare list you want to perform.
3. If you want to provide additional procedures that are not covered by items one or two above, you will need to follow the regular Exception Request policies and procedures. Please do not use attachment # 2 for this request.

If you have any questions, feel free to contact Sandra Knoble at (717) 783-8980 or [sknoble@state.pa.us](mailto:sknoble@state.pa.us).

Sincerely,



Richard H. Lee  
Deputy Secretary for Quality Assurance

Attachment #1- How to Access State and Federal Regulations  
Attachment #2- Form for Expedited Exception Request

Attachment # 1

## HOW TO ACCESS STATE AND FEDERAL REGULATIONS

1) For the Pennsylvania Department of Health ASF regulation (28 Pa. Code § 551.21)

[www.pacode.com/secure/data/028/chapter551/s551.21.html](http://www.pacode.com/secure/data/028/chapter551/s551.21.html)

2) For the Pennsylvania Department of Health regulation for “regular” Exception Requests (28 Pa. Code §§ 51.31 - 51.34)

[www.pacode.com/secure/data/028/chapter51/chap51toc.html](http://www.pacode.com/secure/data/028/chapter51/chap51toc.html)

From Chapter Table of Contents (TOC), link to 51.31, 51.32, 51.33

3) For the federal ASC List of Medicare Approved Procedures

[www.cms.hhs.gov](http://www.cms.hhs.gov)

Select "Medicare"

Select "Professional" drop down list; select "Ambulatory Surgical Centers"

Page down to "Ambulatory Surgical Center Rates"

Select "ASC List of Medicare Approved Procedures"

Select "ASCPUF2005.ZIP"

"Accept" copyright statement

Select "Download the CY2005 in zip file format (215Kb)"

Select "Open"

Select "I Agree"

Select "Excel file 2005\_ALLwith.C"

Attachment # 2 Expedited Exceptions Request to the Division of Acute and Ambulatory Care

**Name of Facility**

**Address of Facility**

**Facility Representative**

**Phone Number**

**Fax Number**

**I certify that I am an authorized representative of the above-named facility and the facility is in good standing with the Department of Health. I am requesting an expedited exception to 28 Pa. Code § 551.21(d) in order to perform the following procedures that are on the List of Medicare Approved ASC Procedures. (Please include the name of the procedure and HCPCS code, if known. If you need additional space, expand the space below, or attach another page.)**

**I understand that the Medicare time limits of 90 minutes operating time, 4 hours of recovery time, and 90 minutes of anesthesia time where general anesthesia is used will apply to the above procedures and will be adhered to by this facility. I also understand that the facility must report all transfers to a hospital as an infrastructure failure under the PA-PSRS system.**

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Signature of individual authorized by the governing  
body to sign on behalf of the ambulatory surgical facility

For fastest response, please e-mail the electronic request to [ra-paexcept@state.pa.us](mailto:ra-paexcept@state.pa.us) and then mail the signed hard copy to:

Sandra Knoble, Director Division of Acute and Ambulatory Care  
Room 532, Health and Welfare Building  
Harrisburg, PA 17120