

The mission of the Florida Society of Ambulatory Surgical Centers is to advance the ambulatory surgical center industry through community awareness and government advocacy and to promote the professionalism of its members through education, networking and the exchange of information.

President's Letter

By *Saul R. Epstein, FSASC President*



2017 marks a year of tremendous work accomplished by FSASC on behalf of our members. One of the most recent successes of FSASC is contained within the pages of an 83 page Final

Order document issued by Judge Elizabeth McArthur, Administrative Law Judge, State of Florida, Division of Administrative Hearings, on November 30, 2017. It concerns a matter FSASC has been involved with, on behalf of FSASC members, for a number of years.

A number of months ago, the Department of Financial Services, Division of Workers' Compensation ("Department") had published a proposal Rule to codify its non-Rule policy that was put into effect in 2015. FSASC felt that this rule (the "Proposed Rule") severely restricts ASCs from obtaining fair treatment for Workers' Compensation Petitions filed with the Department. FSASC, through its Executive Director, Peter Lohrengel, outside legal counsel, myself, and others, participated in various informal meetings with Department staff and also participated in several formal workshops on this matter which were held in Tallahassee. Notwithstanding FSASC's exhaustive

efforts in opposition of the Proposed Rule, the Department, determined to proceed to finalize its Proposed Rule. FSASC's Board of Directors determined that this issue was significant in that the Proposed Rule affected the substantial interests of a FSASC members and it voted in favor of a formal challenge to the Proposed Rule. As such, FSASC filed a "Rule Challenge", which essentially is the filing of a lawsuit against the State of Florida. It is a very big deal, and not to be taken lightly. It is time consuming and expensive, in terms of legal fees and cost.

The Department, with the aligned position of a number of Carriers, who become "intervenor" in this case, vigorously defended its position and challenged not only the substantive position of FSASC, but also its standing to bring the Petition Challenging Proposed Rule on behalf of its members. The initial burden fell on FSASC to prove it had standing and then, once standing was determined that the burden would shift to the Department to prove that the Proposed Rule was not an invalid exercise of delegated legislative authority.

After a 3 day trial, which included Peter Lohrengel being sworn in and testifying on behalf FSASC, the Judge issued a sharply worded opinion which ruled in favor of FSASC. The Final Order includes that (i) FSASC had standing to bring the Rule Challenge, (ii) FSASC's members have

already been directly and immediately harmed by the policies the Department sought to codify as Rules, and (iii) Department was not permitted to "carve-out" exceptions to the all-inclusive scope of the statutory reimbursement dispute process. To view the Final Order, go to www.FSASC.org/final-order..

FSASC's legislative advocacy "arm" will continue to monitor (and advocate on behalf of FSASC members) all legislative proposals that affect the substantial interests of FSASC members, including any proposals to the legislature that, if enacted, would have the same negative impact on ASCs as the now defeated Proposed Rule would have had. I'm sure 2018 will bring a year full of new challenges and triumphs for FSASC and its members! As I discussed in my prior Fall, 2017 Quarter President's Letter and presented during our last annual meeting held in Orlando this past Summer, as your FSASC President, I strongly encourage each of you, as FSASC members (and especially those that treat injured workers), to donate at least \$5,000, if not, \$10,000 per year to your FSASC SurgiPAC, so FSASC can continue to report wins to you, our Members, like this one for which we are extremely happy and proud.

In closing, on behalf of the ASC Board of Directors and the entire FSASC family, I offer best wishes to you and your family this holiday season. ■

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Immediate-Use Steam Sterilization

By Sandra Jones and Patty Spain of Ambulatory Strategies Inc.
and Phenelle Segal of Infection Control Consulting Services

Question:

What is considered an Immediate-Use Steam Sterilization?

Is it the same as flash? Or, is it considered "short cycle"?

Answer:

I asked Patty Spain, CST, EMT, LHRM, of Ambulatory Strategies (www.ambulatorystrategies.com) and Phenelle Segal, RN, CIC, FAPIC, of Infection Control Consulting Services (www.iccs-home.com) to weigh in on this topic. Their experience and insight were helpful in providing clarity about the differences between Immediate-Use Steam Sterilization (IUSS) and short cycle.

I just performed a mock survey in preparation for CMS and AAAHC surveys at a surgery center that had only four cataract instrument trays and rapid case turnover for their high volume of cases. The low number of instrument sets, short cases, and high volume resulted in detailed discussion about their instrument processing. Their sterilizer cycle tape showed "Flash Cycle" with 10 minutes sterilization and 1-minute dry time. They were using rigid containers.

Our first steps were to look for manufacturer's instructions for use (IFU) for instrument cleaning and the sterilizer manufacturer's manuals on sterilizer cycles. We could not find information in the facility on the rigid containers being used. Since the sterilizers were not new, it was also important to go to the manufacturer's

website and learn updates to the instructions for use, especially as it related to IUSS cycle and short cycle processing and the use of rigid containers approved for use in the sterilizer. Since all rigid containers are not created equal, it is essential to assure a rigid container is suitable for use in the sterilizer being used and allows complete air removal, adequate steam penetration and drying. Some containers can be used for Immediate Use Steam Sterilization (IUSS) but not for cycles that allow holding instruments for later use.

Note that if you have most instruments that require 10 minutes of sterilization per the manufacturer's instructions for use and one instrument in the set that requires 20 minutes of sterilization per the IFU, you must always go with the longer sterilization time for all instruments in the tray. Yet, you still need to check if the MIFU for the instruments requiring 10 minutes has a warning about using longer sterilization times.

In 2011 a multi-society position statement changed the terminology "Flash Sterilization" to "Immediate Use Steam Sterilization (IUSS)" to more accurately reflect the variety of steam sterilization cycles used to process items that are to be used promptly. In August 2014, the Centers for Medicare and Medicaid Services (CMS) sent out Survey and Certification Memorandum 09-55 *Flash Sterilization Clarification – FY 2010 Ambulatory Surgical Center (ASC) Surveys* which stated that CMS endorsed the position statement. In February 2015 CMS clarified the fact

that "short cycle" steam sterilization is not the same as IUSS.

IUSS is the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field (AAMI 2011). CMS emphasized the fact that IUSS does not in any way permit deviation from written instructions provided by the device manufacturers, sterilization equipment manufacturers, container/wrap manufacturers and compliance with professional guidelines but it does allow for little or no dry time because it will be used right away. Devices sterilized using the IUSS cycle cannot be stored for later use; the items must be transferred to point of use and used, not remaining in the container for 20 minutes, hours, or days and then used. (Table 1)

The sterile processing technician (SPT) should be able to provide evidence that the sterilizer cycle being used for IUSS is indicated in the instrument's manufacturer's IFU. Guidance must be obtained when the instrument manufacturer's IFUs are not compatible with the sterilizer or container/wrapper instructions for use. If differing instructions cannot be resolved and the instrument is urgently needed, the instrument's manufacturer's instructions must be followed.

"Short Cycle" sterilization is NOT considered IUSS. "Short Cycle" sterilization is a form of terminal sterilization that follows the device manufacturer's IFUs for cleaning, decontamination and rinsing, uses a manufacturer's approved shorter sterilization cycle

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which includes a complete dry time and is packaged in a wrapped or rigid container that is cleared by the FDA for a future use; that is, the instruments and container can be stored per the facility’s event related practices, e.g., for hours or days. (Table 1)

Professional guidelines for IUSS include the following:

- Disassemble and thoroughly clean items in the same manner as when performing regular cycle sterilization.
- Use physical monitors and appropriate chemical indicators with each load.
- A closed sterilization container must be validated for the use in IUSS cycle and differentiated from other containers.
- Aseptic transfer from the sterilizer to the sterile field is followed.
- Items are not stored for future use or subsequent cases.
- A daily biological indicator is used for a test run in an “immediate use” cycle and the results recorded.
- Organization’s leaders ensure training, education, and the competency of staff is validated.
- IUSS use should be part of the center’s quality assessment measures.

IUSS should not be used for sterilizing implants, except in cases of a documented emergency when no other option is available. Additionally, devices that have not been validated with cycle parameters available to the staff

and devices that are intended for single-use only should not be sterilized using IUSS. Use of the IUSS cycle to disinfect instruments used on patients who may have Creutzfeldt-Jakob disease or other prion diseases is also not recommended.

Facilities that use the IUSS cycle will be asked for data by surveyors and citations may be issued based on the data provided. For example, information about action taken to decrease the frequency of IUSS may be considered. Documentation of IUSS use should include the following:

- Items processed
- Patient identification
- Surgeon
- Type of cycle
- Cycle parameters
- Monitoring results
- Date and time of cycle
- Operator information
- Reason for IUSS

Routine use of IUSS presents concerns about lack of time to accomplish adequate pre-cleaning, increased risk of inadvertent contamination during transfer to the

sterile field, damage to the instruments, risks related to wet instruments, and the potential for burns. Therefore, use of IUSS, even when all steps are performed properly, should be limited to situations in which there is an urgent need and insufficient time to process an instrument by using terminal sterilization. Immediate-use steam sterilization should not be used as a substitute for insufficient instrument inventory.

AAMI recently released updated standards and recommended practices. And, keeping up to date with the manufacturers of your sterilizers, cleaners, containers, wrappers, and instruments is essential. Make it a point to check for updates on the manufacturers’ website. You might want to set up a checklist of steps and occasionally observe adherence to the process as part of your quality assessment. If you find differences between the correct steps and actual practice, it is time for a performance improvement project, taking action to reduce or eliminate the discrepancies.

Thank you to Patty Spain and Phenelle Segal for their contributions to this article. ■

Table 1 – IUSS vs Short Cycle

	IUSS	Short Cycle
Cleans, disinfects and rinses per manufacturer’s IFU (including disassembly when needed)	X	X
Uses a rigid container/wrap that is validated for IUSS cycle	X	
Follows manufacturer IFU for container/wrap	X	X
Follows device, container/wrap, and sterilizer approved shorter sterilization cycle	X	X
Use of physical monitors and chemical indicators	X	X
May be wet when aseptically placed on sterile field	X	
Allows for dry time		X
Rigid container/wrap FDA approved for future use		X
Follows professional guidelines	X	X

**Some rigid containers are FDA cleared with no dry time and sterility for up to 30 days.*

Legislative Update



By Mike Cusick, FSASC Legislative Director

As we approach the 2018 session we are facing several interesting times. Nationally congress struggles to complete tasks before

them and regulatory changes are presenting uncertain results. Additionally, like Hollywood and Washington DC, Tallahassee has been rocked recently by allegations of impropriety by state Legislators. One state Senator has resigned and one is under investigation. While not directly of interest to FSASC, these revelations have changed the leadership structure of the Senate. The incoming Democratic Leader of the Senate resigned and the Appropriations Chair in the Senate has been replaced in that position pending an internal investigation. It remains to be seen whether any of this will have a material affect on bills and the process. It is certainly making a lot of people nervous and cautious.

The 2018 Legislative session starts January 9th which is about three months earlier than in previous years. This has created a more intense set of fall committee meetings as the legislature prepares for the session start. As we have discussed in the past the Florida House has been focused on pushing several health care marketplace changes that they believe will lead to high quality and

lower cost care for patients. These changes have passed the House the last two sessions in various forms but have not been embraced by the Florida Senate. This year the House has established a shortened process for moving measures to the Senate. Bills that have previously passed the House multiple times will be referred to only one committee and then take them directly to the House floor. The House has already moved several measures through committee and will take them up possible the first week of the session around January 9th. The Senate is maintaining its normal process of referring bills to multiple committees before they reach the floor.

Although the 2018 session doesn't start until January 9th the Legislature has been busy holding committee meetings and positioning bills in preparation for the session. Already, the House passed several bills that would

affect ASCs if finally enacted. Bills on Workers' Compensation, 23 Hour Care, and patient surveys were adopted in committee in November were priority bills for House leaders that did not pass last session. They are taking up and moving these measures to the floor of the House in preparation for a quick start in January. While there appears to be some interest in the ASC part of HB 23 (SB 250) the Senate has shown no current interest in the Workers' Compensation payment shift to Medicare or the cultural safety survey requirement contained in HB 35.

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Workers' Compensation

Like last session the Florida House is ready to pass a bill that shifts Workers' Compensation payments to a Medicare based system. The House Commerce Committee, chaired by Representative Jim Boyd (R), took up the same bill adopted by the House last session that, among other things, shifts the health care provider payment system to a Medicare based system. The bill, sponsored by the House Commerce Committee (PCB COM 18-01), is being handled by Representative Danny Burgess (R) Zephyrhills.

FSASC Board member Robert Haen, Director of Center One in Jacksonville, spoke against the proposed change to Workers' Compensation during committees on November 14. There is not comparable bill in the Senate for the Workers' Compensation change and FSASC, working in concert with the Florida Hospital Association, is urging Senators not to include the Medicare shift in any effort in the Senate. It is likely to be a battle that will be fought throughout the session.

23 Hour Care

HB 23 by Representative Paul Renner (R) Palm Coast was adopted by the House Health and Human Services Committee in November and will likely be taken up by the full House of Representatives in early January. This bill would allow patients to stay up to 24 hours in an ASC rather than being discharge at

midnight. The bill also creates a new facility license called a recovery care center that if enacted would allow a patient to be discharged from a hospital or ASC to a recovery care center to recover from surgery for up to 72 hours.

The Senate version of this bill, SB 250, by Senator Greg Steube (R) Sarasota only contains the ASC provisions. The Senate bill is expected to be taken up in its first committee, the Health Policy Committee, Chaired by Senator Dana Young (R) Tampa, at the December or early January meeting of that committee. This measure is moving more quickly than in past sessions.

Florida's No Fault Auto Insurance, PIP

Another issue that the House is pushing includes repealing the current no fault auto insurance called PIP and replacing it with mandatory general liability coverage similar to most other states in the country. There is a companion bill in the Senate but it did not go anywhere last session and so far there is not much interest in pushing that bill this year.

Cultural Surveys

HB 35 by Representative Michael Grant (R) Port Charlotte, requires ASCs and Hospitals to conduct patient safety culture surveys and then post the results of those surveys on their website. The bill was passed by the House Health and Human Services Committee this week. This bill has also passed the House during

the last two sessions and is expected to be taken up by the full House early in the session. There is no current effort in the Senate to pass this language.

FSASC expects to see the House push for the repeal of the hospital certificate of need process but again this measure has not been supported in the Senate. There are rumors that the House will propose other price transparency changes that would give consumers more information before selecting a sight of service but there is nothing concrete on this for the moment.

Stay Informed and Make Your Voice Heard

As in past sessions Legislators will file about 2,000 individual bills. FSASC reads all of them and is tracking all that could be relevant to your ability to appropriately serve patients. We will be sending out weekly reports during the session and periodically asking for your help in calling your state legislator urging them to vote up or down on a specific bill.

Thank you in advance for the help and attention. It is important that they know that people back home, not just those of us in Tallahassee care about the decisions that they make. It is also very important that every center participate in SurgiPAC. These funds help FSASC educate legislators and candidates and support those people that, like you, are interested in promoting quality patient care. ■

Heard Around the Country...

CMS Finalizes Payment Rule for 2018

The Centers for Medicare and Medicaid Services (CMS) recently posted the final payment rule for 2018. The rule contains a mix of items that affect ASCs. To begin with, there is an overall average 1.2% increase in reimbursement across all services.

The final rule added three new procedures to the list of approved procedures, namely CPTs 58572, 22858 and 22856. In a disappointing move, CMS refused to approve total knee arthroscopy in the ASC for

Medicare patients. Their argument was that this procedure typically requires more than 23 hours of surgery and recovery time.

The final rule also made adjustments to the ASC Quality Reporting Program. CMS removing the requirement to report data in 2019 (collected in 2018) for ASC prophylactic antibiotic timing, Safe surgery checklist use and ASC volume data for select procedures.

CMS added two new measures that will affect payment determination in 2022. These are: Hospital visits after orthopedic ASC procedures and after Urology ASC procedures.

Finally, CMS continued an indefinite delay on the implementation of the ASC-CAHPS (Consumer Assessment of Healthcare Providers and Systems) program. This gives both CMS and ASCs more time to prepare for this high impact new program during 2018. ■

State Update

FSASC Completes Dispute Resolution Trial

On October 11th and 12th, FSASC argued to a state administrative law judge the merits of its case against the changes that the Division of Workers' Compensation is seeking to make to the Dispute Resolution Rule. The

State is seeking to remove the ability to receive a meaningful determination for any ASC that has entered into a Workers' Compensation contract or managed care agreement with an insurer. The changes to the rule go

so far as to say that even an alleged contract will lead to a non-binding determination.

To view the Final Order, go to www.FSASC.org/final-order.

DWC Advances new Manual

The Florida Division of Workers' Compensation (DWC) published a new version of the proposed 2017 ASC Provider Manual in late October. The Manual contains several textual changes and a complete update and

expansion of the MRA table. FSASC provided testimony to the Division about the manner in which the new Manual treats Associated Disposable Instrumentation associated with an implant. It is unclear whether the new

Manual will be finalized in time to replace the 2016 Manual which currently awaits legislative ratification. Until such a time as the Legislature acts, the 2015 Manual in current use will remain in place.

AHCA Close to Final on Transparency Rule

The Agency for Health Care Administration (AHCA) is expected to file the Transparency Rule associated with the 2016 Transparency legislation that requires certain postings on ASC websites and increased patient notifications.

The statute is quite detailed and it has been difficult for AHCA to craft a rule that provides any additional explanation on how to interpret the statute without exceeding its statutory authority. The final rule is relatively short and adds a few measures to the

comprehensive list set out in statute. FSASC will notify members as soon as the rule is notified as final. There will be several new items that will be in effect at that time that must be addressed immediately. ■

Join FSASC at the Quality & Risk Management Conference this April

There are headlines every day about the medical field and mistakes that should have been avoided. How do you keep these events from happening at your center? How do you create a culture of safety that engages every staff member?

In 2018, the FSASC Education committee is helping ASC administrators and risk managers learn about “Balancing Risk in Your ASC” at the Quality & Risk Management Conference. Make plans to attend April 19-20 in Orlando at the Renaissance

Orlando at SeaWorld. This conference is set to have national speakers and experts on ASC issues and will include a session addressing specific ASC infection control issues.

Administrators, risk managers and other quality leaders in the ASC are invited to attend and join with other ASC leaders to discuss best practice strategies for reducing risk and improving patient safety. With a convenient and central location, this conference is ideal for centers that need specific ASC education close to home.

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Save the Date! FSASC 2018 Annual Conference & Trade Show

With the new year just around the corner, the FSASC Education Committee is busy making plans and confirming speakers for an agenda that aims to please the busy ASC professional.

Next summer, learn about the latest industry trends as you meet up with old friends, make new contacts and learn about the latest industry trends. In 2018, the FSASC Annual Conference & Trade Show will take place July 18-20, 2018 in Orlando at the

Hyatt Regency Grand Cypress.

FSASC Annual Conference continues to be one of the best industry values. It's never too early

to mark your calendars as FSASC invites you to bring your family to Orlando and enjoy the theme park experience! ■

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Melbourne Surgery Center
Merritt Island Surgery Center
Northwest Florida Surgery Center

Panama City Surgery Center, LLC
Physicians Day Surgery Center, Inc.
Physicians Surgical Care Center
Surgery Center at Doral

GOLD LEVEL

Florida Endoscopy & Surgery Center, LLC
Florida Eye Clinic A.S.C.
Lakeland Surgical & Diagnostic Center

Surgery Center of Ocala
Surgery Center of Volusia, LLC
Tampa Bay Endoscopy Center

West Park Surgery Center

SILVER LEVEL

All Saints Surgery Center
Ambulatory Surgery Center-Tampa
Atlantis Outpatient Center
Bay Area Physicians Surgery Center
Bayonet Point Surgery and
Endoscopy Center
Bayside Ambulatory Center
Belleair Surgery Center
Brandon Surgery Center
Cornerstone Surgicare LLC
Countryside Surgery Center
Doctors Same Day Surgery Center
Florida Surgery Center

Gulf Coast Endoscopy Center of Venice
Gulf Coast Surgery Center
Gulf Pointe Surgery Center
HCA Ambulatory Surgery Division
Jacksonville Surgery Center
Kissimmee Surgery Center
Miami Lakes Surgery Center
New Port Richey Surgery Center
North County Surgicenter
North Florida Surgical Pavilion
North Miami Beach Surgical Center
Orange Park Surgery Center
Outpatient Surgical Services

Palms West Surgicenter
Parkside Surgery Center
Riverwalk Surgery Center
Same Day Surgery Center of Orlando
St. Lucie Surgery Center
Surgery Center at Coral Springs
Surgery Center at St. Andrews
Surgery Center of Aventura, LTD
Surgical Park Center
Tallahassee Outpatient Surgery Center
Tampa Eye and Specialty Surgery Center
Venture Ambulatory Surgical Center

BRONZE LEVEL

Central Florida Surgicenter
Day Surgery Center
Promenades Surgery Center, LLC

South Broward Endoscopy Center
St. Mark's Surgical Center, LLC
Surgical Development Systems, Inc

The Endoscopy Center of Pensacola
Winter Haven Ambulatory
Surgical Center, LLC