



**Department
of Health**

Proposed Oversight Model

Article 28 Diagnostic and
Treatment Centers in which Certain
Outpatient Procedures are
Performed

**Division of Hospitals and Diagnostic & Treatment Centers
New York State Department of Health**

Background and Proposed Model

Background

Outpatient Procedures can be performed in:

- Private Practice (Office Based Surgery);
- Licensed Article 28 Ambulatory Surgery Center (Freestanding Diagnostic and Treatment Center);
- Licensed Article 28 Ambulatory Surgery Center (Hospital extension clinic).

Background: Private Practice

- Private practices performing routine outpatient care are not required to be licensed under Article 28.
- Private practices performing invasive and/or surgical procedures using moderate or greater sedation/anesthesia are required under Public Health Law (PHL) §§ 230-d and 2998-e to be accredited by an approved organization and submit adverse event reports to the Department's Office Based Surgery (OBS) Program.

Background: Licensed Sites

- Outpatient sites at which routine patient care is performed are certified in one or more service categories based on the services provided, e.g., Primary Care, Other Medical Specialties.
- Outpatient sites at which procedures meeting the current definition of ambulatory surgery are performed, are certified in the appropriate ambulatory surgery service category (e.g., Gastroenterology, Orthopedics, Ophthalmology, Multi-Specialty), are federally certified and are known as Ambulatory Surgery Centers or ASCs.
- Either can be freestanding or hospital based.

Healthcare Delivery Evolution

- Health care delivery is evolving, driven by:
 - New knowledge;
 - New technology and techniques to perform procedures;
 - Desire to provide care in the most cost effective settings;
 - Patient and physician preference, etc.
- There is an interest among providers to perform certain invasive diagnostic, therapeutic and/or surgical procedures in appropriate settings beyond those currently approved;
- The Department is exploring allowing these procedures to be performed in D&TCs, subject to certain parameters.

Considerations

- Patient safety and assurance of quality of care must be preserved.
- Patient selection is key--the right patient to undergo the right procedure in the right setting.
- Procedures must be conducted consistent with regulatory requirements and professional standards assuring patient safety and quality.

Considerations, continued

Procedures must be performed in settings with the ability to provide associated care guided by factors including, but not limited to:

- Procedural urgency
- Invasiveness
- Associated infection control requirements
- Complexity of the procedure.

Considerations, continued

- Administration of sedation and anesthesia must be consistent with regulatory requirements and professional standards and performed in settings with the ability to provide sedation and anesthesia related care
- Compliance with all components of the NYS Surgical and Invasive Procedure Protocol requiring patient identification, site marking, pre-operative/pre-procedural verification, and “time outs”.

The Proposal

Allow certain procedures to be performed, and/or sedation and/or anesthesia administered, in certain outpatient settings, D&TC's, D&TC extension clinics, hospital extension clinics, within specified limits and established requirements for:

- Patient selection
- Physical plant
- Types of procedures
- Sedation/anesthesia levels
- Patient monitoring and recovery

The Proposal, continued

- Preserve the current D&TC operating certificate services:
 - Primary Care and/or Other Medical Specialties
 - Ambulatory Surgery
- Add a new service:
 - Outpatient Procedures

Existing Service Categories

- Primary Care and/or Other Medical Specialties: Providers are limited to performing non-invasive procedures involving local or peripheral regional anesthesia and/or minimal sedation which may be performed in an exam room.
- Ambulatory Surgery: Providers may perform non-invasive, minimally invasive and/or invasive procedures and/or administer deep sedation, spinal anesthesia or general anesthesia in an operating room or class 3 Imaging room.

Proposed New Service Category

Outpatient Procedures: Providers may perform non-invasive and/or minimally invasive procedures and/or administer up to moderate sedation, peripheral regional and/or epidural anesthesia in a procedure room or class 2 or 3 Imaging room, subject to limits on patient selection, types of procedures and levels of sedation, with additional requirements for physical plant and staffing.

Proposed Model

	Article 28 D&TC Freestanding or Hospital Extension	Article 28 D&TC Freestanding or Hospital Extension	OBS Practice	Article 28 D&TC Freestanding or Hospital Extension ASC
Operating Certificate Service Categories	Primary Care and/or Other Medical Specialties	Outpatient Procedures (Proposed)	----	Ambulatory Surgery
Procedural Invasiveness/IC needs*				
Non-invasive	X	X	X	X
Minimally Invasive		X*	X	X
Invasive			X	X
Energy Assisted Devices: External application	X*	X	X	X
Energy Assisted Devices: Internal application		X	X	X
Sedation/Anesthesia Related Factors				
Type of Anesthesia				
Local; peripheral regional	X	X	X	X
Epidural		X	X	X
Regional anesthesia of major upper and/or lower extremities or central nerve routes			X	X
Spinal anesthesia			X	X
General anesthesia			X	X
Level of Sedation				
Minimal	X	X	X	X
Moderate		X	X	X
Deep			X	X

- Within limits as defined by the Department

Additional Considerations for the Outpatient Procedures Service Category

- Determine type of CON Application;
- Develop an oversight model e.g., accreditation (most likely consistent with Office Based Surgery requirements) or survey;
- Establish a process to evaluate the appropriateness of procedures proposed to be performed in this setting.

Next Steps

- Meetings to obtain stakeholder feedback.
- Develop application process for clinics seeking to apply for the new *Outpatient Procedures* service category.
- Develop guidance for providers to assist in selecting the appropriate service category and setting.
- Determine appropriate oversight model.
- Allow the service to be added based on guidance while developing regulations.

Architectural Requirements

Outpatient Settings and Associated Services

Table 1: Criteria for Determining Appropriate Outpatient Setting and Associated Service Designation

Certified Service		Medical Services	Outpatient Procedures		Ambulatory Surgery		Inpatient Surgery	
			Off-Site	On-Campus	Off-Site	On-Campus		
1. Criteria Applicable to Clinical Surveillance / Architecture and Engineering								
a.	Urgency	Routine	Yes	Yes	Yes	Yes	Yes	Yes
		Urgent	No	No	Yes	Yes	Yes	Yes
		Emergency	No	No	No	No	No	Yes
b.	Invasiveness	Non-invasive (Diagnostic & Therapeutic)	Yes	Yes	Yes	Yes	Yes	Yes
		Minimally Invasive (Procedural)	No	Yes	Yes	Yes	Yes	Yes
		Invasive (Surgical)	No	No	No	Yes	Yes	Yes
c.	Sterile Field/ Environment	Aseptic field	Yes	Yes	Yes	Yes	Yes	Yes
		Sterile environment	No	No	No	Yes	Yes	Yes
d.	Sedation Levels	Minimal (Min)	Yes	Yes	Yes	Yes	Yes	Yes
		Moderate (Mod)	No	Yes	Yes	Yes	Yes	Yes
		Deep	No	No	No	Yes	Yes	Yes
e.	Anesthesia Types	Local; peripheral regional (PR)	Yes	Yes	Yes	Yes	Yes	Yes
		Epidural (Epi)	No	Yes	Yes	Yes	Yes	Yes
		Central Regional Anes. (CR)	No	No	No	Yes	Yes	Yes
		Spinal anesthesia (SA)	No	No	No	Yes	Yes	Yes
		General anesthesia (GA)	No	No	No	Yes	Yes	Yes

Outpatient Settings and Associated Services

Table 1: Criteria for Determining Appropriate Outpatient Setting and Associated Service Designation

Certified Service		Medical Services	Outpatient Procedures		Ambulatory Surgery		Inpatient Surgery	
			Off-Site	On-Campus	Off-Site	On-Campus		
2. Architectural and Engineering Criteria								
a.	Pre-Procedure Area	Dedicated preparation & monitoring space and staffing	No	Yes	Yes	Yes	Yes	Yes
b.	Room Types	Exam	Yes	Yes	Yes	Yes	Yes	Yes
		Treatment	Yes	Yes	Yes	Yes	Yes	Yes
		Procedure	No	Yes	Yes	Yes	Yes	Yes
		Operating Room	No	No	No	Yes	Yes	Yes
		Minimally Invasive (Procedural)	No	Yes	Yes	Yes	Yes	Yes
c.	Imaging Room (Classifications)	Invasive (Surgical)	No	No	No	Yes	Yes	Yes
		Minimally Invasive (Diagnostic)	Yes	Yes	Yes	Yes	Yes	Yes
		Invasive (Procedural)	No	Yes	Yes	Yes	Yes	Yes
d.	Energy Assisted Devices	Class 3 Room (Surgical)	No	No	No	Yes	Yes	Yes
		Externally applied	Yes	Yes	Yes	Yes	Yes	Yes
e.	Post-procedure Area	Internally applied	No	Yes	Yes	Yes	Yes	Yes
		Dedicated post-procedure monitoring space and staffing	No	Yes	Yes	Yes	Yes	Yes

Outpatient Settings and Associated Services

Table 1: Criteria for Determining Appropriate Outpatient Setting and Associated Service Designation

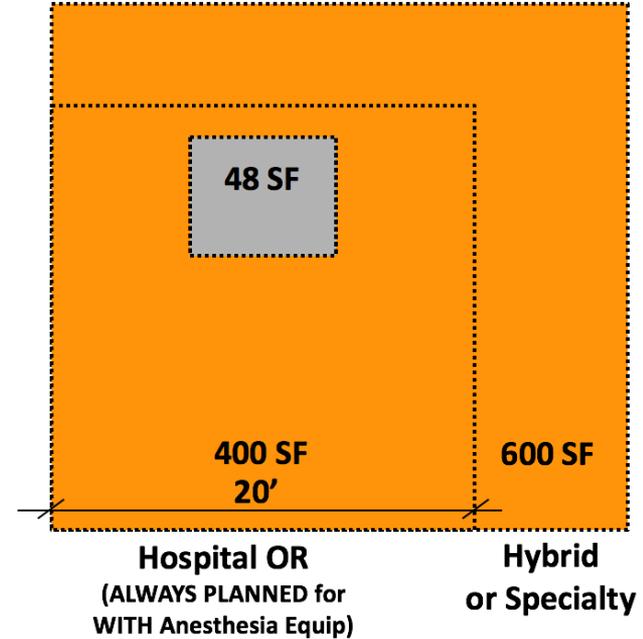
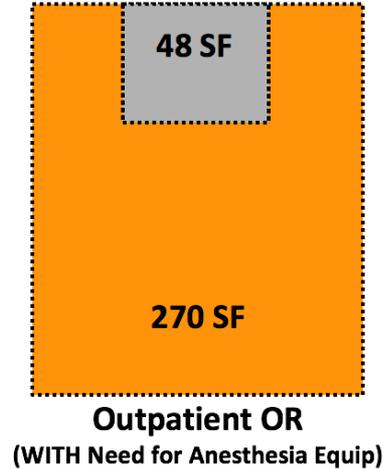
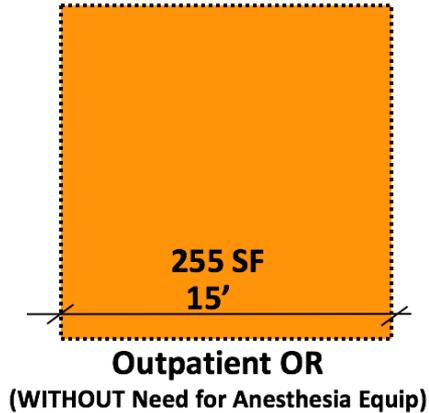
Certified Service		Medical Services	Outpatient Procedures		Ambulatory Surgery		Inpatient Surgery	
			Off-Site	On-Campus	Off-Site	On-Campus		
3. Clinical Surveillance Criteria								
a.	Patient Related Factors	Absolute Exclusion Criteria	Yes	Yes	Yes	Yes	Yes	No
		Relative Exclusion Criteria	Yes	Yes	Yes	Yes	Yes	No
b.	Procedural Complexity	Procedure length	< 1hr	< 2hr	< 3hr	< 6hr	< 6hr	No limit
		Potential blood loss	< 100ml	< 300ml	< 300ml	< 500ml	< 500ml	No limit
		Risk of needing to emergently convert to an open procedure	No	No	No	Yes	Yes	Yes
		Risk of unexpected adverse event that the setting is not equipped to handle & requiring emergent transfer to higher level of care.	None	Minimal	Low	Low	Low-Mod	NA
c.	Recovery Factors	Time to meet post-procedure discharge criteria	< 1hr	< 2hr	< 4hr	< 24h	< 24h	NA
		Need for recovery time/post-procedure monitoring	No	< 4hr	< 6hr	< 24h	< 24h	NA

Criteria for Determining Room Types

Table 2. Criteria for Determining Appropriate Room Type
(Refer to Appendix for description of criteria and sources)

Classifications			Room Types				Imaging Rooms		
			Exam Room	Treatment Room	Procedure Room	Operating Room	Class 1 Imaging	Class 2 Imaging	Class 3 Imaging
1.	Procedure Type ¹	Non-invasive (Diagnostic)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Minimally Invasive (Procedural)	No	No	Yes	Yes	No	Yes	Yes
		Invasive (Surgical)	No	No	No	Yes	No	No	Yes
2.	Sedation Levels	Minimal (Min)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Moderate (Mod)	No	No	Yes	Yes	No	Yes	Yes
		Deep	No	No	No	Yes	No	No	Yes
3.	Anesthesia Types	Local; peripheral regional (PR)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Epidural (Epi)	No	No	Yes	Yes	No	Yes	Yes
		Regional anesthesia of major upper or lower extremities or central nerve routes (CR)	No	No	Yes	Yes	No	Yes	Yes
		Spinal anesthesia (SA)	No	No	No	Yes	No	No	Yes
		General anesthesia (GA)	No	No	No	Yes	No	No	Yes
4.	Sterile Field	Aseptic field	Yes	Yes	Yes	Yes	Yes	Yes	Yes
		Sterile environment	No	No	No	Yes	No	No	Yes

Room Dimensions



Space Requirements

KEY



Patient area



Sterile field where staff and physician work



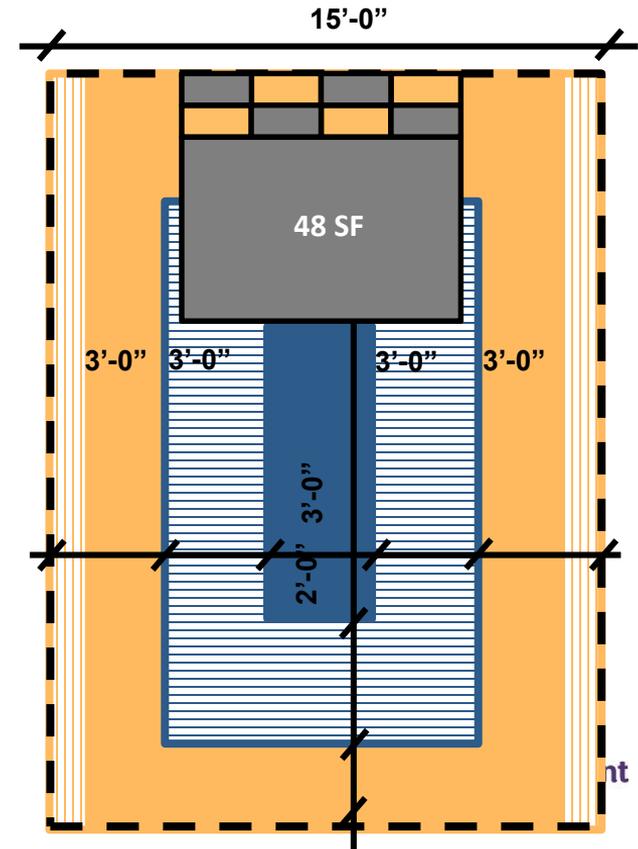
Circulation pathway and movable equipment zone



Movable equipment zone where the required movable equipment is stored and provides for door swing and opening of fixed drawers or opening of door and drawers on carts

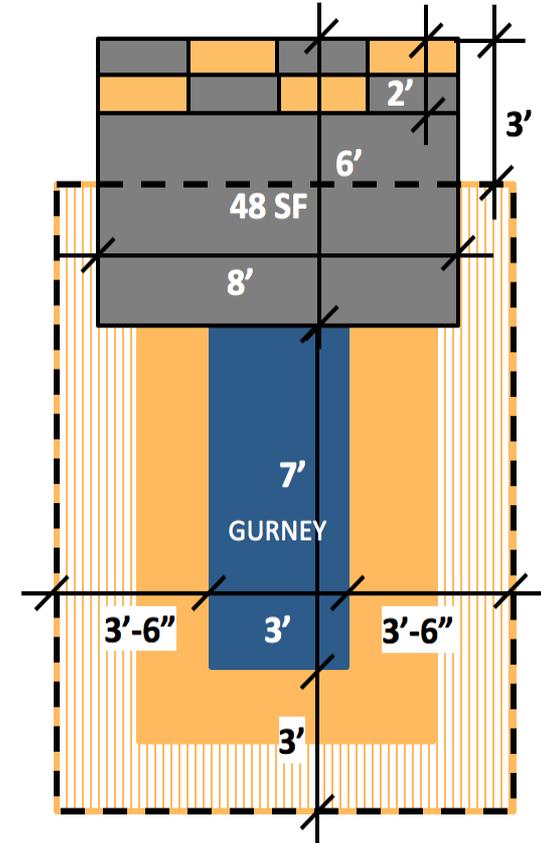
Space Requirements-Outpatient OR

- Minimum clear floor area: 270 sq. ft.
- Minimum width 15 ft.
- Clearances:
 - 6 ft. on sides of table/chair
 - 5 ft. at head and foot
 - 6 ft. x 8 ft. at head
 - 6 ft. anesthesia work zone



Space Requirements-Procedure Room

- Clear floor area reduced to 130 sq. ft.
- Clearances reduced to:
 - 3 ft. 6 in. on sides table/gurney/chair
 - 3 ft. at head and foot
- EXCEPTION where anesthesia machine and cart are used:
 - Clear floor area: 160 sq. ft.
 - Clearances: 6 ft. at head



Questions?