
CMS Physical Environment Compliance Challenges

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Financial Interest Disclosure

- The presenter provides Health Care Facility consulting services, related to assessment of regulatory compliance & facility design/planning/construction
- He is on retainer with the Accreditation Association for Ambulatory Health Care as their physical environment specialist

Necessary background

- CMS Conditions are formerly adopted through a process of proposal, public comment, reassessment, and adoption/abandonment
- CMS “maintains” (without review or comment) the State Operations Manual, Appendix L, as “guidance to surveyors”
- Appendix L is enforced as if regulation
Medicare Facility Compliance
Title 42, Code of Federal Regulations

§ 416.44 Conditions for Coverage (CfCs) - Environment.

✓ The ASC must have a safe and sanitary environment . . . to protect the health and safety of patients.
✓ ORs designed to assure clinical & physical safety of everyone involved
✓ Separate Waiting and Recovery areas
✓ Comply with NFPA 101, 2000 edition

Necessary background

✓ Adopting any particular edition of the NFPA 101® Life safety Code® brings with it all “contemporary editions” of every NFPA code and standard in any way referenced from the LSC. Such as the “CMS-current 2000 ed. of NFPA 101, is contemporary to the 1999 NFPA 99, the 1999 NFPA 70, the 1998 NFPA 25, etc. for a dozen+ others.

Medicare Physical Environment
The Real Survey Requirements

✓ Spatial & Operational clarifications as published in the CMS State Operations Manual appendix L (Rev. 137, 04-01-15)
✓ Construction and Fire Safety issues per National Fire Protection Association documents . . . . starting with NFPA 101 “The Life Safety Code,” and following through numerous other NFPA Standards as referenced therefrom
SOM Appendix L

The Fun Begins

✓ 12/2009: Detailed narrative about “distinct entity” requirements -- “wholly separate from any other” . . . “separated from other facilities or operations within the same building by walls with at least a one-hour separation” . . . temporal option for non-clinical space; but still within ASC’s defining fire walls . . .

CMS Memos/Policy

✓ 05/21/2010: “Clarification of long standing policy” relative to waiver considerations for shared waiting rooms.

✓ Real effect: No facilities seeking new agreements with CMS (after memo date) may apply for such a waiver.

SOM Appendix L

Pressure relationships between O.R.s and adjacent connected spaces

✓ 2013: Procedure rooms are ORs
✓ 6/2013: Temp & humidity maintained per accepted standards of practice
✓ 8/2013: Temp humidity & airflow, records demonstrating adherence, example national standards (ANSI 170, FGI, etc.), separate temperature control in each O.R.
SOM Appendix L

- Pressure relationships between O.R.s and adjacent connected spaces
  - 4/2015: Procedure rooms are ORs but don’t have to meet the same standards
  - 4/2105: Existing ORs only need to meet standards in place when they were first approved

SOM Appendix L

- The evolving requirement for relative humidity in ASC O.R.s
  - Step 1: 30% to 60% per NFPA 99 inpatient
  - Step 2: 20% to 60% per AORN
  - Step 3: below 30% requires evaluation of manufacturer’s recommendations to assure safe environment
  - In all cases you must adopt and adhere to a national standard

2000 code set of NFPA 101

- None of the referenced standards have changed... Yet

- Survey scrutiny and focus have changed DRAMATICALLY since 2012
2000 code set of NFPA 101 post-2012 surveys

- Deemed Status accrediting bodies are required to perform a complete and comprehensive LSC survey on 3 year maximum cycle (with every survey)
- EXPERT LSC surveyors have become the norm, and result in frequent/numerous citations never before identified by State or CMS surveyors – literal compliance: no equivalency interpretation allowed

2000 code set of NFPA 101 post-2012 surveys

- The most frequent issues relate to “operational requirements” for inspection, testing, and maintenance (ITM) - long in the codes but never before a survey priority
- Initial testing/approval documents for Fire Alarm, Sprinkler System, Medical Gas system, & Generator Sets

2000 code set of NFPA 101 post-2012 surveys

- High frequency ITM for Fire Alarm System & Sprinkler System a very common problem.
- Fire emergency plans rarely correct . . . the “E” in RACE, and confusion over distractors (NOT defend in place).
- Essential Electrical Systems often out of compliance for general anesthesia use

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2000 code set of NFPA 101 post-2012 surveys
- Generator set ITM often inadequate – installation & weekly inspection details
- Medical Gas System valve locations a fairly common problem
- Loosely hanging fabrics often not labeled for compliance with NFPA 701, and supporting documentation not present

CMS tracking of surveys
- A small portion of deemed status surveys are followed by duplicate CMS surveys to compare findings, aka identifying “deficiency disparities.”
- Deemed survey organizations are expected to work to minimize such disparities; but the deck is stacked by the presumption that CMS is always right

CMS tracking of surveys
Top Ten disparities
- Automatic fire sprinkler systems – 14%
- Doors – 11%
- Means of egress – 10%
- Electrical – 8.5%
- Hazardous Areas – 8.25%
CMS tracking of surveys

Top Ten disparities

- Fire Alarm - 8.25%
- Smoke/Fire Barriers - 6.25%
- Emergency Lighting - 4.3%
- Medical gases - 3.9%
- Generator Set - 3.9%

CMS Categorical Waivers

Rules for use:
- Must formally adopt any waivers you will use.
- Must inform survey team BEFORE they survey the applicable issues – opening conference is expectation
- Must adhere to all parameters attached to the waiver

CMS Categorical Waivers

2013:
- 1. Medical Gas Master Alarms - Category/Level 1 piped medical gas systems only; Allows one of multiple master alarms to be computer-based
- 2. Openings in Exit Enclosures; Allows existing doors to limited mechanical spaces from exit enclosures (no fuel fired equipment, no combustible storage, only in sprinklered buildings, etc.)
CMS Categorical Waivers

2013:

✓ 3. Emergency Generators and Standby Power Systems; Allows 90 minute annual load bank for diesel generator sets instead of 2-hours (when required)

✓ 6. Extinguishing Requirements; allows for a reduction in the testing frequencies for sprinkler system vane-type and pressure switch type waterflow alarm devices

CMS Categorical Waivers

2013:

✓ 7. Clean Waste & Patient Record Recycling Containers; Allows for an increase in size of containers used solely for recycling clean waste or for patient records awaiting destruction, outside of a hazardous storage area to be a maximum of 96-gallons

CMS Categorical Waivers

2014:

✓ 8. Power strip use in health care facilities, especially related to patient care areas; Allows for use of 2 specific UL-rated power strips in patient care areas, and 1 specific UL-rating in non-patient areas. Must be permanently attached to cart or assembly of equipment plugged in to it. No open plugs for other use. Requires load calculations to assure no more than 75% of plug strip rating. ITM responsibilities and more . . .
CMS Limitations

- Central Office sets policy and publishes guidance
- Regional offices are not required to adhere to CMS policy . . . and may interpret CMS intent differently
- Many CMS surveyors are State Health Department employees who blend State & CMS requirements

Resources

- CMS: “CMS State Operations Manual Appendix L”
  - Search Internet for exact title
- NFPA documents and standards:
  - Get “Handbook” versions when available
- NFPA.org (free access, if you are very patient)
- WELdesigns.com - resources white papers

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