

COMPLIANCE CHECKLIST**OP3: Outpatient Pharmacies**

The following checklist is intended to be used in the plan review applications for health care facilities submitted to the Massachusetts Department of Public Health. This checklist summarizes and references the applicable requirements from the Licensure Regulations and the 2018 Edition of the FGI Guidelines for Design and Construction of Outpatient Facilities. Applicants must verify compliance of the plans submitted to the Department with all referenced requirements from the Licensure Regulations and FGI Guidelines when completing this Checklist. A separate Checklist must be completed for each nursing unit, hospital or clinic department, or clinical suite.

Other jurisdictions, regulations and codes may have additional requirements which are not included in this checklist, such as:

- NFPA 101 Life Safety Code (2012) and applicable related standards contained in the appendices of the Code
- State Building Code (780 CMR)
- Accreditation requirements of The Joint Commission
- CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities
- USP 797 & USP 800
- Regulations of the Massachusetts Board of Registration in Pharmacy
- Accessibility Guidelines of the Americans with Disabilities Act (ADA)
- Architectural Access Board Regulations (521 CMR)
- Local Authorities having jurisdiction.

Instructions:

1. All requirement lines must be completed according to the following instructions and included in the plan submissions for Self-Certification Process or Abbreviated Review Process.
2. This checklist must be completed by the project architect or engineer based on the design actually reflected in the plans at the time of completion of the checklist.
3. Each requirement line (____) of this Checklist must be completed exclusively with one of the following marks, unless otherwise directed in the checklist. If a functional space is not affected by a renovation project, the mark "E" may be indicated on the requirement line (____) before the name of the functional space (associated requirements on indented lines below that name, or associated MEP requirements do not have to be completed in this case). If more than one functional space serves a given required function (e.g. patient room or exam room), that clarification should be provided in the Project Narrative, and the requirement lines are understood to only address the functional spaces that are involved in the project.

X = Requirement is met, for new space, for renovated space, or for existing direct support space for an expanded service.

☒ = Check box under section titles or individual requirements lines for optional services or functions that are not included in the project area.

E = Requirement relative to an existing suite or area that has been *licensed* for its designated function, is *not affected* by the construction project and *does not pertain to a required direct support space* for the specific service affected by the project.

W = Waiver requested for specific section of the Regulations or FGI Guidelines, where hardship in meeting requirement can be demonstrated (a Physical Plant Waiver Form must be completed for each waiver request). An explicit floor plan or plan detail must be attached to each waiver request.

4. All room functions marked with "X" must be shown on the plans with the same name labels as in this checklist.
5. Mechanical, electrical & plumbing requirements are only partially mentioned in this checklist. The relevant section of the FGI Guidelines must be used for project compliance with all MEP requirements and for waiver references.
6. Oxygen, vacuum, medical air, and waste anesthesia gas disposal outlets (if required) are identified respectively by the abbreviations "OX", "VAC", "MA", & "WAGD".
7. Requirements referenced with "FI" result from formal interpretations from the FGI Interpretations Task Group.
8. The location requirements including asterisks (*) refer to the definitions of the Glossary in the beginning section of the FGI Guidelines and reproduced in this checklist.

Facility Name:

DoN Project Number: (if applicable)

Facility Address:

Satellite Name: (if applicable)

Building/Floor Location:

Satellite Address: (if applicable)

Submission Dates:

Initial Date:

Revision Date:

Project Description:

Architectural Requirements**Building Systems Requirements**

2.1-4.2

PHARMACY SERVICES

2.1-4.2.1.2

Location:

- (1) ___ pharmacy room or suite located in same building as outpatient services it supports
- (2) ___ controlled access to room or suite

2.1-4.2.1.3

Medication Safety Zone Design:

2.1-3.8.8.1(2)

Design Promoting Safe Medication Use:

- (a) ___ medication safety zones located out of circulation paths
- (b) ___ work space designed so that staff can access information & perform required tasks
- (c) ___ work counters provide space to perform required tasks

Lighting:

___ Task-specific lighting level min. 100 foot-candles

2.1-3.8.8.1(2)
(d)

2.1-3.8.8.2

- (1) ___ medication preparation room
 ☐ check if not included in project
- (a) ___ work counter
 ___ handwashing station
 ___ lockable refrigerator
 ___ locked storage for controlled drugs
 ___ sharps containers
 ☐ check if not included in project
- (b) ___ self-contained medication dispensing units
 ☐ check if not included in project
 ___ room designed with space to prepare medications

Ventilation:

___ Min. 4 air changes per hour

Table 8.1/

Lighting:

___ Task lighting

Policy

2.1-3.8.8.1(2)

2.1-4.2.2

Pharmacy Areas:

2.1-4.2.2.1

- ___ dispensing facilities
 ☐ check if not included in project
- (1) ___ room or area for receiving, unpacking & inventory control of materials used in pharmacy
- (2) ___ work counters & space for automated and/or manual dispensing activities
- (3) ___ extemporaneous compounding area
 ☐ check if not included in project
 ___ sink & counter space for drug preparation
- (4) ___ area for reviewing & recording

Ventilation:

___ Min. 4 air changes per hour
 ___ Positive pressure

Table 8.1/
Policy

Architectural Requirements**Building Systems Requirements**

- (5) ☐ area for temporary storage
exchange & restocking of carts
☐ check if not included in project
(only if medication carts are not used)
- (6) ☐ security provisions for drugs & personnel in dispensing counter area

- 2.1-4.2.2.2 ☐ manufacturing facilities
☐ check if not included in project

- (1) ☐ bulk compounding area

- (2) ☐ provisions for packaging & labeling

- (3) ☐ quality control area

- 2.1-4.2.2.3 ☐ storage cabinets shelves and/or separate rooms or closets

- (1) ☐ bulk storage

- (2) ☐ active storage

- (3) ☐ refrigerated storage

- (4) ☐ storage for volatile fluids & alcohol

- (5) ☐ secured lockable storage for narcotics & controlled drugs

- (6) ☐ equipment & supply storage

- 2.1-4.2.3 Sterile Work Areas for Intravenous (IV) Drugs:
☐ check if not included in project

- 2.1-4.2.3.1(1) ☐ pharmacy layout precludes unrelated traffic through non-hazardous drugs (NHD) preparation rooms & hazardous drugs (HD) preparation rooms

- (2) ☐ robotic systems used in either positive pressure NHD preparation room or negative pressure HD preparation room
☐ check if not included in project
☐ separate systems & not pass from one room to other

- 2.1-4.2.3.2 ☐ Non-Hazardous (NHD) preparation room
☐ check if not included in project
☐ IV solutions are prepared in pharmacy sterile work area with laminar-flow workstation designed for product protection

Ventilation:

- ☐ Min. 4 air changes per hour
☐ Positive pressure

Table 8.1/
Policy

Architectural Requirements**Building Systems Requirements**

- (1) ☐ laminar-flow workstation equipped with HEPA filter
- (2) ☐ laminar-flow workstation has visible pressure gauge for detection of filter leaks or defects
- 2.1-4.2.3.3 ☐ Hazardous drug preparation room
- ☐ separate room provided for preparation of hazardous drug IV admixtures under Class II (type A2 B1 or B2) or Class III biological safety cabinet

2.1-4.2.8 **SUPPORT AREAS FOR PHARMACY**

- 2.1-4.2.8.3 ☐ Access to information
- (1) ☐ provision for cross-checking medication & drug profiles of individual patients
- (2) ☐ provision for access to poison control reaction data & drug information
- 2.1-4.2.8.4 ☐ Separate room or area be provided for office functions
- 2.1-4.2.8.7 ☐ Handwashing station
- ☐ handwashing station provided either in anteroom or immediately outside room where open medications are prepared
- 2.1-4.2.8.8 ☐ Outpatient medication consultation area
- ☐ check if not included in project (only if medication is not dispensed directly to patients)
- 2.1-4.2.8.13 ☐ Equipment & supply storage for unit dose procedure
- ☐ check if not included in project (only if unit dose procedure is not used)
- ☐ additional space & equipment to accommodate supplies packaging labeling & storage including space for carts

2.1-4.2.9 **SUPPORT AREAS FOR PHARMACY STAFF**

- 2.1-4.2.9.2 (may be shared with other departments)
- 2.1-4.2.9.1 ☐ Lounge & locker facilities
- ☐ readily accessible* to pharmacy staff

Architectural Requirements

- ☐ Staff toilet room
- ☐ readily accessible* to pharmacy staff

Building Systems Requirements

Ventilation:

- ☐ Min. 10 air changes per hour Table 8.1/
Policy
- ☐ Exhaust
- ☐ Negative pressure
- ☐ No recirculating room units

***LOCATION TERMINOLOGY:**

Directly accessible: Connected to the identified area or room through a doorway, pass-through, or other opening without going through an intervening room or public space

Adjacent: Located next to but not necessarily connected to the identified area or room

Immediately accessible: Available either in or adjacent to the identified area or room

Readily accessible: Available on the same floor or in the same clinic as the identified area or room

Architectural Details & MEP Requirements**2.1-7.2.2 ARCHITECTURAL DETAILS****CORRIDOR WIDTH:**

- 2.1-7.2.2.1 ☐ Min. 44"
- IBC 1018.2 **or**
- ☐ Detailed code review incorporated in Project Narrative

- 421 CMR 6.00 ☐ Corridors include turning spaces for wheelchairs

- (2) ☐ Corridors used for stretcher & gurney transport have min. corridor or aisle width of 6'-0"
- ☐ check if not included in project

2.1-7.2.2.2 CEILING HEIGHT:

☐ Min. ceiling height 7'-10" in other areas

2.1-7.2.2.3 DOORS & DOOR HARDWARE:

- (1) Door Type:
- (a) ☐ doors between corridors, rooms, or spaces subject to occupancy swing type or sliding doors
- (b) ☐ sliding doors
- ☐ check if not included in project
- ☐ manual or automatic sliding doors comply with NFPA 101
- ☐ detailed code review incorporated in Project Narrative
- ☐ no floor tracks
- (2) Door Opening:
- (a) ☐ min. 34" clear door width
- ☐ min. 83.5" clear door height

- (3) Door Swing:
- (a) ☐ doors do not swing into corridors except doors to non-occupiable spaces (e.g. environmental services rooms & electrical closets) & doors with emergency break-away hardware
- (4) ☐ Lever hardware or push/pull latch hardware
- 2.1-7.2.2.8 **HANDWASHING STATIONS:**
- (3)(a) ☐ Handwashing station countertops made of porcelain, stainless steel, solid-surface materials or impervious plastic laminate assembly
- (3)(b) ☐ Countertops substrate
- ☐ check if not included in project
- ☐ marine-grade plywood (or equivalent material) with impervious seal
- (4) ☐ Handwashing station casework
- ☐ check if not included in project
- ☐ designed to prevent storage beneath sink
- (5) ☐ Provisions for drying hands
- ☐ check if not included in project (only at hand scrub facilities)
- (a) ☐ hand-drying device does not require hands to contact dispenser
- (b) ☐ hand-drying device is enclosed to protect against dust or soil
- (6) ☐ Liquid or foam soap dispensers

2.1-7.2.3 SURFACES**2.1-7.2.3.1 FLOORING & WALL BASES:**

- (1) _____ Flooring surfaces cleanable & wear-resistant for location
- (3) _____ Smooth transitions provided between different flooring materials
- (4) _____ Flooring surfaces including those on stairways are stable, firm & slip-resistant
- (5) _____ Floors & wall bases of all areas subject to frequent wet cleaning are constructed of materials that are not physically affected by germicidal or other types of cleaning solutions
- (6)(a) _____ Floors are monolithic & integral coved wall bases are at least 6" high & tightly sealed to wall in IV & chemotherapy preparation room

2.1-7.2.3.2 WALLS & WALL PROTECTION:

- (1)(a) _____ Wall finishes are washable
- (1)(b) _____ Wall finishes near plumbing fixtures are smooth, scrubbable & water-resistant
- (4) _____ Wall protection devices & corner guards durable & scrubbable

2.1-7.2.3.3 CEILINGS:

- (1) _____ Ceilings provided in all areas except mechanical, electrical & communications equipment rooms
- (a) _____ Ceilings cleanable with routine housekeeping equipment
- (b) _____ Acoustic & lay-in ceilings where used do not create ledges or crevices

(2) Semi-Restricted Areas:

- ☐ check if not included in project
- (a) _____ ceiling finishes are scrubbable, non absorptive, non perforated, & capable of withstanding cleaning with chemicals
- (b) _____ lay-in ceilings
 - _____ gasketed or each ceiling tile weighs at least one pound per square foot
- (c) _____ use of perforated tegular serrated or highly textured tiles not are permitted in semi-restricted areas

or

- _____ ceilings of monolithic construction

2.1-8.2**HEATING VENTILATION & AIR-CONDITIONING (HVAC) SYSTEMS UTILITIES:****Part 3/6.1
Part 3/6.1.1****Ventilation Upon Loss of Electrical Power:**

- _____ space ventilation & pressure relationship requirements of Table 8.1 are maintained for All Rooms & Operating Rooms in event of loss of normal electrical power
- ☐ check if not included in project

**Part 3/6.1.2
Part 3/6.1.2.1****Heating & Cooling Sources:**

- _____ heat sources sufficient to accommodate facility needs (reserve capacity) even when any one of heat sources or essential accessories is not operating due to breakdown or routine maintenance

Part 3/6.1.2.2**Central cooling systems greater than 400 tons (1407 kW) peak cooling load**

- ☐ check if not included in project
- _____ number & arrangement of cooling sources sufficient to support facility operation plan upon breakdown or routine maintenance of any one of cooling sources

**Part 3/6.2
Part 3/6.2.1****AIR-HANDLING UNIT (AHU) DESIGN:**

- _____ AHU casing is designed to prevent water intrusion, resist corrosion & permit access for inspection & maintenance

Part 3/6.3**OUTDOOR AIR INTAKES & EXHAUST DISCHARGES:****Part 3/6.3.1
Part 3/6.3.1.1****Outdoor Air Intakes:**

- _____ located min. of 25'-0" from cooling towers & all exhaust & vent discharges
- _____ outdoor air intakes located such that bottom of air intake is at least 6'-0" above grade
- _____ air intakes located away from public access
- _____ all intakes are designed to prevent entrainment of wind-driven rain

Part 3/6.3.1.3

- _____ intakes on top of buildings
- ☐ check if not included in project
- _____ located with bottom of air intake min. of 3'-0" above roof level

Part 3/6.3.1.4	<input type="checkbox"/> intake in areaway <input type="checkbox"/> check if <u>not</u> included in project <input type="checkbox"/> bottom of areaway air intake opening is at least 6'-0" above grade <input type="checkbox"/> bottom of air intake opening from areaway into building is at least 3'-0" above bottom of areaway	Part 3/6.8	ENERGY RECOVERY SYSTEMS: <input type="checkbox"/> check if <u>not</u> included in project
Part 3/6.3.2	Contaminated Exhaust Discharges: <input type="checkbox"/> check if <u>not</u> included in project	Part 3/6.8.1	<input type="checkbox"/> Located upstream of Filter Bank No. 2
Part 3/6.3.2.1	<input type="checkbox"/> ductwork within building is under negative pressure for exhaust of contaminated air (i.e. air from HD sterile compounding pharmacy) <input type="checkbox"/> exhaust discharge outlets with contaminated air located such that they reduce potential for re-circulation of exhausted air back into building	Part 3/6.8.2	<input type="checkbox"/> All room exhaust systems are not used for energy recovery
Part 3/6.3.2.2	<input type="checkbox"/> exhaust discharge outlets with contaminated air is arranged to discharge to atmosphere in vertical direction at least 10 feet above adjoining roof level <input type="checkbox"/> exhaust discharge outlets from laboratory work area chemical fume hoods discharge with stack velocity of at least 2500 fpm <input type="checkbox"/> exhaust discharge outlets from chemical fume hoods is located not less than 25 feet horizontally from outdoor air intakes, openable windows/doors & areas that are normally accessible to public	Part 3/6.8.3	<input type="checkbox"/> Energy recovery systems with leakage potential <input type="checkbox"/> check if <u>not</u> included in project <input type="checkbox"/> arranged to minimize potential to transfer exhaust air directly back into supply airstream <input type="checkbox"/> designed to have no more than 5% of total supply airstream consisting of exhaust air <input type="checkbox"/> not used from these exhaust airstream sources: Hazardous Drugs Buffer Rooms
Part 3/6.4	FILTRATION: <input type="checkbox"/> Outpatient spaces one filter bank MERV 7	Part 3/7	SPACE VENTILATION:
Part 3/6.7	AIR DISTRIBUTION SYSTEMS:	Part 3/7.1.a	<input type="checkbox"/> Complies with Table 8.1 <input type="checkbox"/> Air movement is from clean to less-clean areas
Part 3/6.7.1	<input type="checkbox"/> Maintain pressure relationships required in tables 7.1 in all modes of HVAC system operation <input type="checkbox"/> Spaces that have required pressure relationships are served by fully ducted return systems or fully ducted exhaust systems	Part 3/7.1.a.1	<input type="checkbox"/> Min. number of total air changes required for positive pressure rooms is provided by total supply airflow
Part 3/6.7.2	Air Distribution Devices: <input type="checkbox"/> supply air outlets comply with Table 6.7.2	Part 3/7.1.a.3	<input type="checkbox"/> Min. number of total air changes required for negative pressure rooms is provided by total exhaust airflow <input type="checkbox"/> Entire minimum outdoor air changes per hour required by Table 8.1 for each space meet filtration requirements of Section 6.4
Part 3/6.7.3	Smoke Barriers: <input type="checkbox"/> HVAC zones coordinated with compartmentation to minimize ductwork penetrations of fire & smoke barriers.	Part 3/7.1.a.4	<input type="checkbox"/> Air recirculation through room unit <input type="checkbox"/> check if <u>not</u> included in project <input type="checkbox"/> complies with Table 8.1 <input type="checkbox"/> room unit receive filtered & conditioned outdoor air <input type="checkbox"/> serve only a single space <input type="checkbox"/> provides min. MERV 6 filter located upstream of any cold surface so that all of air passing over cold surface is filtered
		2.1-8.3	ELECTRICAL SYSTEMS
		2.1-8.3.2	ELECTRICAL DISTRIBUTION & TRANSMISSION
		2.1-8.3.2.2	Panelboards:
		(1)	<input type="checkbox"/> all panelboards accessible to health care tenants they serve
		(4)	<input type="checkbox"/> panelboards not located in exit enclosures or exit passageways
		2.1-8.3.6	ELECTRICAL RECEPTACLES
			<input type="checkbox"/> Receptacles in patient care areas are provided according to Table 2.1-1

2.1-8.4 **PLUMBING SYSTEMS**

2.1-8.4.2 Plumbing & Other Piping Systems:

2.1-8.4.2.1(3) ☐ no plumbing piping exposed overhead or on walls where possible accumulation of dust or soil may create cleaning problem

2.1-8.4.2.5 Heated Potable Water Distribution Systems:

- (2) ☐ heated potable water distribution systems serving patient care areas are under constant recirculation
- ☐ non-recirculated fixture branch piping length max. 25'-0"
- (3)(a) ☐ no installation of dead-end piping (except for empty risers mains & branches for future use)
- (3)(c) ☐ any existing dead-end piping is removed
- (3)(b) ☐ check if not included in project
- (4)(a) ☐ water-heating system supplies water at following range of temperatures: 105–120°F

2.1-8.4.2.6 Drainage Systems:

- (1)(a) ☐ drainage piping installed above ceiling of or exposed in rooms listed below piping have special provisions to protect space below from leakage & condensation
- pharmacy “clean rooms”
 - electronic data processing areas
 - electrical rooms
- (1)(b) ☐ drip pan for drainage piping above ceiling of sensitive area
- ☐ check if not included in project
- ☐ accessible
- ☐ overflow drain with outlet located in normally occupied area that is not open to restricted area

2.1-8.4.3 **PLUMBING FIXTURES**

2.1-8.4.3.1(1) ☐ Materials used for plumbing fixtures are non-absorptive & acid-resistant

2.1-8.4.3.2 Handwashing Station Sinks:

- (1) ☐ sinks are designed with basins that will reduce risk of splashing to areas where medications are prepared
- (2) ☐ sink basins have nominal size of no less than 144 square inches
- ☐ sink basins have min. dimension 9 inches in width or length
- (3) ☐ sink basins are made of porcelain, stainless steel or solid-surface materials

- (5) ☐ water discharge point of faucets is at least 10" above bottom of basin
- (7) ☐ anchored so that allowable stresses are not exceeded where vertical or horizontal force of 250 lbs. is applied
- (8) ☐ sinks used by staff, patients, & public have fittings that can be operated without using hands (may be single-lever or wrist blade devices)
- (a) ☐ blade handles
- ☐ check if not included in project
- ☐ at least 4 inches in length
- ☐ provide clearance required for operation
- (b) ☐ sensor-regulated water fixtures
- ☐ check if not included in project
- ☐ meet user need for temperature & length of time water flows
- ☐ designed to function at all times and during loss of normal power