

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 2022 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. Any 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:

Project Description:

Initial Date:

Revision Date:

ARCHITECTURAL REQUIREMENTS**Building Systems Requirements**

2.1-4.2

PHARMACY SERVICES

2.1-4.2.1.2

Location:

- ___ Pharmacy room or suite located in same building as outpatient services it supports

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

Ventilation:

- ___ Min 4 air changes per hour

Table 8-1

(a)

- ___ work counter
- ___ handwashing station
- ___ lockable refrigerator
- ___ locked storage for controlled drugs
- ___ sharps containers
☐ check if not included in project

Lighting:

- ___ Task lighting

2.1-3.8.8.1(2)

(b)

- ___ self-contained medication dispensing units
☐ check if not included in project
- ___ room designed with space to prepare medications

2.1-4.2.2

Pharmacy areas:

2.1-4.2.2.1

Security:

- ___ access to room or suite is controlled

2.1-4.2.2.2

___ Dispensing facilities

- ☐ check if not included in project

(1)

- ___ room or area for receiving unpacking & inventory control of materials used in pharmacy

Ventilation:

- ___ Min 4 air changes per hour
 ___ Positive pressure

Table 8-2

(2)

- ___ work counters & space for automated and/or manual dispensing activities

(3)

- ___ area for reviewing & recording prescriptions

(4)

- ___ area for temporary storage exchange & restocking of carts
☐ check if not included in project (only if medication carts are not used)

(5)

- ___ security provisions for drugs & personnel in dispensing counter area commensurate with risks identified in security risk assessment

ARCHITECTURAL REQUIREMENTS**Building Systems Requirements**

- 2.1-4.2.2.3 ☐ Manufacturing facilities
☐ check if not included in project
- (1)(a) ☐ bulk compounding area or patient-specific unit dose compounding area
☐ sink
☐ counter space for drug preparations
- (1)(b) ☐ provisions for packaging & labeling
- (1)(c) ☐ quality control area
- (2) Pharmaceutical compounding types:
- (a) ☐ Nonsterile Preparations:
☐ check if not included in project
☐ Project Narrative indicates that requirements of USP <795> are met
- (b) ☐ Sterile Preparations:
☐ check if not included in project
☐ Project Narrative indicates that requirements of USP <797> are met
- ☐ Hazardous Drugs-Handling:
☐ check if not included in project
- (c) ☐ Project Narrative indicates that requirements of USP <800> are met
- 2.1-4.2.2.4 ☐ Storage
(cabinets, shelves and/or separate rooms or closets)
- (1) ☐ bulk storage
- (2) ☐ active storage
- (3) ☐ refrigerated storage
- (4) ☐ storage for volatile fluids & alcohol in accordance with applicable fire safety codes for substances involved
- (5) ☐ secured lockable storage for narcotics & controlled drugs
- (6) ☐ hazardous drug storage
☐ check if not included in project
☐ refrigerators & freezers located in dedicated room.
- (7) ☐ storage for general supplies & equipment not in use

Ventilation:

☐ Min 4 air changes per hour

Table 8-1

☐ Positive pressure

Ventilation:

☐ Min 4 air changes per hour

Table 8-1

☐ Positive pressure

ARCHITECTURAL REQUIREMENTS**Building Systems Requirements**

- 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
- (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
☐ check if not included in project
 _____ separate room provided for preparation of hazardous drug IV admixtures under Class II (type A2 B1 or B2) or Class III biological safety cabinet
- 2.1-4.2.8.4 _____ Outpatient medication consultation area
☐ check if not included in project
 (only if no medication is dispensed directly to patients from pharmacy area)
- 2.1-4.2.8.7 _____ Handwashing station
 _____ provided either in anteroom or immediately outside room where open medication is prepared
- 2.1-4.2.8.13 _____ Additional 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

ARCHITECTURAL REQUIREMENTS**Building Systems Requirements**

2.1-4.2.8

SUPPORT AREAS FOR PHARMACY

2.1-4.2.8.2

Office space:

(1)

___ separate room provided for office functions if pharmacy provides 450 prescriptions per day or more

or

(2)

___ location of administrative workstations in dispensing area permitted in lieu of office for pharmacy that provides fewer than 450 prescriptions per day

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)

2.1-4.2.8.9

___ Eyewash facilities

☐ check if not included in project

(only if hazardous drugs are not compounded or manipulated in way that can produce airborne particles)

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

2.1-4.2.9.1

(may be located outside pharmacy area & shared with other services provided in outpatient health care facility)

2.1-3.9.1

___ Staff lounge

☐ check if not included in project

___ handwashing station

ARCHITECTURAL REQUIREMENTS**Building Systems Requirements**

2.1-3.9.3 ☐ Storage for staff (e.g., locking drawers, cabinets, lockers for staff personal effects)
☐ readily accessible to individual work areas

2.1-4.2.9.2 ☐ Staff changing area
☐ check if not included in project
 (only if no sterile compounding activities are performed in pharmacy)

2.1-3.9.4.1

(1) ☐ lockers

(2) ☐ toilets

Ventilation:

☐ Min 10 air changes per hour Table 8-1

☐ Exhaust

☐ Negative pressure

☐ No recirculating room units

(3) ☐ handwashing stations

(4) ☐ space for changing clothes

(5) ☐ provision for separate storage for clean and soiled work attire

***LOCATION TERMINOLOGY:**

Directly accessible: Connected to the identified area or room through doorway pass-through or other opening without going through 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

2.1-7.2.2.2 **CEILING HEIGHT:**
 (1) ☐ Min. height 7'-6" in corridors & normally unoccupied spaces
 (2) ☐ Min. height 7'-6" above floor of suspended tracks, rails & pipes located in traffic path
☐ 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

☐ 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

Door Opening:

☐ min 32" clear door width

☐ min 83.5" clear door height

Door Swing:

☐ doors do not swing into corridors except doors to non-occupiable spaces (e.g. environmental services rooms & electrical closets) & doors with emergency breakaway hardware

☐ 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 rooms listed below
- Pharmacy compounding room & anteroom
- ☐ check if not included in project
- 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
- 2.1-8.2 **HEATING VENTILATION & AIR-CONDITIONING (HVAC) SYSTEMS UTILITIES:**
- Part 3/6.1 Heating & Cooling Sources:
- Part 3/6.1.2 ☐ 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
- 3/6.1.2.1 Central cooling systems greater than 400 tons (1407 kW) peak cooling load
- Part 3/6.1.2.2 ☐ 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 **AIR-HANDLING UNIT (AHU) DESIGN:**
- Part 3/6.2.1 ☐ 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 Outdoor Air Intakes:
- Part 3/6.3.1.1 ☐ 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 ☐ intake in areaway
☐ check if not included in project
☐ bottom of areaway air intake opening is at least 6'-0" above grade
☐ bottom of air intake opening from areaway into building is at least 3'-0" above bottom of areaway

Part 3/6.3.2 Contaminated Exhaust Discharges:
☐ check if not included in project

- Part 3/6.3.2.1 ☐ ductwork within building is under negative pressure for exhaust of contaminated air (i.e. air from HD sterile compounding pharmacy)
☐ exhaust discharge outlets with contaminated air located such that they reduce potential for recirculation of exhausted air back into building

- Part 3/6.3.2.2 ☐ exhaust discharge outlets with contaminated air is arranged to discharge to atmosphere in vertical direction at least 10'-0" above adjoining roof level
☐ exhaust discharge outlets from laboratory work area chemical fume hoods discharge with stack velocity of at least 2500 fpm
☐ exhaust discharge outlets from chemical fume hoods is located not less than 25'-0" horizontally from outdoor air intakes openable windows /doors & areas that are normally accessible to public

Part 3/6.4 **FILTRATION:**
☐ Outpatient spaces one filter bank MERV 7

Part 3/6.7 **AIR DISTRIBUTION SYSTEMS:**
 Part 3/6.7.1 ☐ Maintain pressure relationships required in tables 7.1 in all modes of HVAC system operation
☐ Spaces that have required pressure relationships are served by fully ducted return systems or fully ducted exhaust systems

Part 3/6.7.2 **Air Distribution Devices:**
☐ supply air outlets comply with Table 6.7.2

Part 3/6.7.3 **Smoke Barriers:**
☐ HVAC zones coordinated with compartmentation to minimize ductwork penetrations of fire & smoke barriers.

Part 3/6.8.3 ☐ Energy recovery systems with leakage potential
☐ check if not included in project
☐ arranged to minimize potential to transfer exhaust air directly back into supply airstream
☐ designed to have no more than 5% of total supply airstream consisting of exhaust air
☐ not used from these exhaust airstream sources: Hazardous Drugs Buffer Rooms

Part 3/7 **SPACE VENTILATION:**

Part 3/7.1.a ☐ Complies with Table 8-1
☐ Air movement is from clean to less-clean areas

Part 3/7.1.a.1 ☐ Min number of total air changes required for positive pressure rooms is provided by total supply airflow
 Part 3/7.1.a.3 ☐ Min number of total air changes required for negative pressure rooms is provided by total exhaust airflow

Part 3/7.1.a.4 ☐ Entire min outdoor air changes per hour required by Table 8.1 for each space meet filtration requirements of Section 6.4

Part 3/7.1a.5 ☐ Air recirculation through room unit
☐ check if not included in project
☐ complies with Table 8-1
☐ room unit receive filtered & conditioned outdoor air
☐ serve only single space
☐ provides min MERV 8 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) ☐ all panelboards accessible to health care tenants they serve
 (4) ☐ panelboards not located in exit enclosures or exit passageways

2.1-8.3.6 **ELECTRICAL RECEPTACLES**

☐ 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 & faucets 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 & during loss of normal power

2.2-8.3**2.2-8.3.4****ELECTRICAL SYSTEMS****EMERGENCY EGRESS LIGHTING**

- ☐ Automatic emergency lighting
- or**
- ☐ Facility has total floor area of not more than 1,000 sf is located at grade level & has direct access to exits to grade