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:
- 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:

__________________________

Facility Address:

__________________________

Satellite Name: (if applicable)

__________________________

Satellite Address: (if applicable)

__________________________

Project Description:

__________________________

Facility Name: ____________________________

DoN Project Number: (if applicable)

__________________________

Facility Address:

__________________________

Satellite Name: (if applicable)

__________________________

Satellite Address: (if applicable)

__________________________

Project Description:

__________________________

MDPH/DHCFLC 12/19 OP3
### Architectural Requirements

<table>
<thead>
<tr>
<th>Rule</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1-4.2</td>
<td><strong>PHARMACY SERVICES</strong></td>
</tr>
<tr>
<td>2.1-4.2.1.2</td>
<td>Location:</td>
</tr>
<tr>
<td>(1)</td>
<td>___ pharmacy room or suite located in same building as outpatient services it supports</td>
</tr>
<tr>
<td>(2)</td>
<td>___ controlled access to room or suite</td>
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<thead>
<tr>
<th>Rule</th>
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<tbody>
<tr>
<td>2.1-4.2.1.3</td>
<td>Medication Safety Zone Design:</td>
</tr>
<tr>
<td>2.1-3.8.8.1(2)</td>
<td>Design Promoting Safe Medication Use:</td>
</tr>
<tr>
<td>(a)</td>
<td>___ medication safety zones located out of circulation paths</td>
</tr>
<tr>
<td>(b)</td>
<td>___ work space designed so that staff can access information &amp; perform required tasks</td>
</tr>
<tr>
<td>(c)</td>
<td>___ work counters provide space to perform required tasks</td>
</tr>
</tbody>
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<th>Rule</th>
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<tbody>
<tr>
<td>2.1-3.8.8.2</td>
<td>___ medication preparation room</td>
</tr>
<tr>
<td>(a)</td>
<td>___ work counter</td>
</tr>
<tr>
<td></td>
<td>___ handwashing station</td>
</tr>
<tr>
<td></td>
<td>___ lockable refrigerator</td>
</tr>
<tr>
<td></td>
<td>___ locked storage for controlled drugs</td>
</tr>
<tr>
<td></td>
<td>___ sharps containers</td>
</tr>
<tr>
<td></td>
<td>□ check if not included in project</td>
</tr>
<tr>
<td>(b)</td>
<td>___ self-contained medication dispensing units</td>
</tr>
<tr>
<td></td>
<td>□ check if not included in project</td>
</tr>
<tr>
<td></td>
<td>___ room designed with space to prepare medications</td>
</tr>
</tbody>
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<tr>
<td>2.1-4.2.2</td>
<td><strong>Pharmacy Areas:</strong></td>
</tr>
<tr>
<td>2.1-4.2.2.1</td>
<td>___ dispensing facilities</td>
</tr>
<tr>
<td></td>
<td>□ check if not included in project</td>
</tr>
<tr>
<td>(1)</td>
<td>___ room or area for receiving, unpacking &amp; inventory control of materials used in pharmacy</td>
</tr>
<tr>
<td>(2)</td>
<td>___ work counters &amp; space for automated and/or manual dispensing activities</td>
</tr>
<tr>
<td>(3)</td>
<td>___ extemporaneous compounding area</td>
</tr>
<tr>
<td></td>
<td>□ check if not included in project</td>
</tr>
<tr>
<td></td>
<td>___ sink &amp; counter space for drug preparation</td>
</tr>
<tr>
<td>(4)</td>
<td>___ area for reviewing &amp; recording</td>
</tr>
</tbody>
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### Building Systems Requirements

<table>
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<tbody>
<tr>
<td>2.1-3.8.8.1(2)</td>
<td>Ventilation:</td>
</tr>
<tr>
<td></td>
<td>___ Min. 4 air changes per hour</td>
</tr>
<tr>
<td></td>
<td>___ Positive pressure</td>
</tr>
<tr>
<td></td>
<td>□ check if not included in project</td>
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<tr>
<td>2.1-3.8.8.1(2)</td>
<td>Lighting:</td>
</tr>
<tr>
<td></td>
<td>___ Task-specific lighting level</td>
</tr>
<tr>
<td></td>
<td>min. 100 foot-candles</td>
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<tr>
<td>2.1-3.8.8.1(2)</td>
<td>Lighting: Policy</td>
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<td>□ check if not included in project</td>
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### Architectural Requirements

<table>
<thead>
<tr>
<th>(5)</th>
<th>area for temporary storage exchange &amp; restocking of carts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ check if not included in project</td>
</tr>
<tr>
<td></td>
<td>(only if medication carts are not used)</td>
</tr>
</tbody>
</table>

| (6) | security provisions for drugs & personnel in dispensing counter area |

#### 2.1-4.2.2.2

| (1) | bulk compounding area |
|     | □ check if not included in project |

| (2) | provisions for packaging & labeling |

| (3) | quality control area |

#### 2.1-4.2.2.3

| (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 |

| □ check if not included in project |

| □ separate systems & not pass from one room to other |

#### 2.1-4.2.3.2

| □ check if not included in project |

| □ IV solutions are prepared in pharmacy sterile work area with laminar-flow workstation designed for product protection |
Architectural 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  
___ 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

2.1-7.2.2.1 CORRIDOR WIDTH:

___ Min. 44”
___ 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

(1) ______

(2) ______

2.1-7.2.2.3 DOORS & DOOR HARDWARE:

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

(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 breakaway 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

(4) ___ Handwashing station casework

☐ check if not included in project

(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) 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
2.1-7.2.3.4 Semi-Restricted Areas:
☐ check if not included in project
(a) ceiling finishes are scrubable, non absorptive, non perforated, & capable of withstanding cleaning with chemicals
(b) 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
2.1-8.2.2 UTILITIES:
Part 3/6.1 Ventilation Upon Loss of Electrical Power:
☐ space ventilation & pressure relationships 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 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 3/6.2 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:
☐ 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 feet 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 feet 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:
☐ 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 3/6.8  Energy Recovery Systems:
☐ check if not included in project

Part 3/6.8.1  Located upstream of Filter Bank No. 2
Part 3/6.8.2  All room exhaust systems are not used for energy recovery

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

Part 3/7.1.a.1  Air movement is from clean to less-clean areas
Part 3/7.1.a.3  Min. number of total air changes required for positive pressure rooms is provided by total supply airflow
Part 3/7.1.a.4  Entire minimum outdoor air changes per hour required by Table 8.1 for each space meet filtration requirements of Section 6.4

Part 3/7.1.a.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 a single space
☐ 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) 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) any existing dead-end piping is removed □ 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
(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) □ 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

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