



DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITY
LICENSURE & CERTIFICATION
99 Chauncy Street
Boston, MA 02111

Attestation

Addition of Mobile & Portable Units

Addition of MOBILE and PORTABLE UNITS

Purpose and Scope:

This Attestation is to be completed by **existing, licensed hospitals or clinics** who are proposing to add a Mobile or Portable Unit (as defined below) for the delivery of organized, ambulatory health services related to provision of medical, dental, physical rehabilitation, laboratory, diagnostic radiology or mental health services that may include preventative health, routine physical examinations, low risk screening, and health education services. Such mobile or portable services are provided for the convenience of patients off the licensed premises of an existing hospital or clinic.

Approval:

This Attestation form identifies specific areas for which an applicant/licensee must address in order to receive approval for the addition of a Mobile or Portable Unit. Completion of this Attestation form does not constitute approval of licensure for the Mobile or Portable Unit by the Department of Public Health (DPH).

DPH approval of a Mobile Unit, Portable Unit or Mobile/Portable Unit as an extension of services provided by an existing, licensed clinic or hospital, will be considered under the Special Projects provision of state licensure regulations (105 CMR 140.025 and 105 CMR 130.051) **and is contingent upon the applicant's/licensee's compliance with all relevant regulations** under 105 CMR 140.000 *Licensure of Clinics*, or 105 CMR 130.000 *Licensure of Hospitals* and the provision of quality care in accordance with applicable standards of practice, state and federal regulations and the conditions detailed therein. This Attestation form serves as supporting documentation that the applicant/licensee is in compliance with such regulations and is prepared to provide Mobile or Portable services.

In accordance with 105 CMR 130.110 of the Hospital Licensure Regulations, and 105 CMR 140.110 of the Clinic Licensure Regulations, the Department may visit and inspect the hospital or clinic at any time, without prior notice, in order to determine the hospital's or clinic's compliance with state law and applicable Licensure Regulations (105 CMR 130.000 or 105 CMR 140.000) and to make a determination regarding the approval of a Mobile or Portable Unit. All parts of the hospital or clinic, all staff and activities, and all records of the hospital or clinic are subject to such visit and inspection.

Definitions:

For the purposes of this document, the following definitions apply:

- **Facility:** A "facility" is defined as a physical building licensed as a clinic or clinic satellite under 105 CMR 140.000, or a hospital or hospital satellite under 105 CMR 130.000.
- **Host Site:** A "host site" is an out-of-facility/out-of-office location in which a Portable Health Unit delivers services. Host sites are pre-determined by the Portable Health Unit provider and the Portable Health Unit provider maintains a schedule for visits to these sites. Host sites can/may include



community environments including long-term care facilities, assisted living facilities, corporate/business locations, community centers, social service agency, churches, etc. Host sites shall not be a campus or satellite of the licensee. Host sites shall not include commercially rented office space rented by the licensee and shall not include the patient's home.

- **Mobile Unit:** A "Mobile Unit" delivers licensed services exclusively within a specially equipped, self-contained vehicle which may be driven, moved, towed or transported from one location to another (such as a van, RV or trailer). Equipment, supplies and other needed items are available in, and all services are provided within, the Mobile Unit. A Mobile Unit may be: (a) an extension/addition of services provided by a clinic or hospital with an existing, licensed physical site, or (b) a clinic that is exclusively mobile, with no licensed physical building in which services are provided.
- **Portable Unit:** A "Portable Unit" is a vehicle that only transports equipment, supplies and/or personnel to a host site location at which the licensee will provide licensed services. Equipment, supplies and other needed items are transported to and from the host site by Portable Unit staff, provided, however, that furnishings, equipment and supplies that are not easily transported or do not require special security measures may be stored in a storage area at a host site. A Portable Unit may be: (a) an extension/addition of services provided by a clinic or hospital with an existing, licensed physical site, (b) an addition/extension of services provided by a Mobile Unit, or (c) the licensee may be a clinic that is exclusively portable, with no licensed physical building or Mobile Unit in which services are provided.
- **Mobile/Portable Unit:** A "Mobile/Portable Unit" is a Mobile Unit from which, from time to time, equipment and supplies may be removed to offer services at a location outside the Mobile Unit at which the licensee will provide licensed services, which is not a campus or satellite of the licensee or the patient's home.



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Attestation

Addition of Mobile & Portable Units

Attestation for Operation of a MOBILE or PORTABLE UNIT

TO BE COMPLETED BY AN EXISTING, LICENSED HOSPITAL OR CLINIC

FACILITY INFORMATION

Facility Name: _____ License #: _____

Address: _____

Business Address: _____

Administrator Name: _____

Tel #: _____ Email: _____

PROPOSED PROGRAM INFORMATION

Mobile/Portable Unit Name: _____
(if different)

Service Delivery Model: Mobile Unit Portable Unit Mobile/Portable Unit
(check all that apply)

Services: Medical Dental Mental Health
(check all that apply) Optometry Laboratory Radiology

Other: _____

Scope of Program: Exclusively mobile/portable (no physical building)
 Extension of existing licensed provider (parent clinic or hospital)

Name of person completing form: _____

Title: _____

Tel #: _____ E-Mail: _____

Attestation:

The undersigned representative of the provider hereby attests that this facility is in compliance with all applicable state and federal regulations and the information provided in this document is accurate and complete and will remain as stated below.

Name and Title (Please Print)	Signature	Date
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DIRECTIONS:

If an existing licensed hospital or clinic wishes to add a Mobile, Portable or Mobile/Portable Health Unit, the conditions detailed below apply and must be addressed as part of the Department’s process to obtain approval to operate. Approval to operate a Mobile or Portable Unit is contingent upon compliance with all relevant regulations under 105 CMR 140.000 *Licensure of Clinics*, or 105 CMR 130.000 *Licensure of Hospitals* and the provision of quality care in accordance with applicable standards of practice and state and federal regulations.

Part I: LICENSURE STATUS

Directions: Please check the appropriate item below regarding licensure status.

Licensure Status

- This attestation is for the addition of a Mobile, Portable or Mobile/Portable Health Unit to be provided **as an extension of services of an existing clinic or hospital licensed** by the Department of Public Health.

Regulation Review

- The applicant/licensee and other relevant individuals as appropriate have read, and are familiar with, the requirements of the appropriate regulations (please check one):
 - 105 CMR 130.000 Licensure of Hospitals
 - 105 CMR 140.000 Licensure of Clinics

Part II: ADMINISTRATIVE STRUCTURAL REQUIREMENTS

Directions: The following items are applicable to both Mobile and Portable Units. Place a check mark in the box for each item for which compliance exists. If items marked “if applicable” do not apply to this Mobile or Portable Unit, please indicate by checking “N/A”. For the purposes of this form, the term “provider” refers to the parent hospital or clinic that is seeking to add the Mobile or Portable Unit.

Item

Administration

- The governing body of the provider approved the establishment of the Mobile or Portable Unit and this is so documented in meeting minutes.
- An organizational chart delineates the provider’s responsibility for the Mobile or Portable Unit.
- There is a pre-determined schedule denoting the fixed, scheduled location(s) of the Mobile or Portable Unit, as applicable, and the provider has/will notify the Department of this schedule.

Policies and Procedures

- There are policies and procedures in place which reflect current standards of practice governing the delivery of services by the Mobile or Portable Unit, including, but not limited to policies and procedures for:
 - services to be performed
 - exchange and transport of equipment and supplies
 - handling of waste and contaminated equipment
 - infection control
 - informed consent, including consent for the treatment of minors



<input checked="" type="checkbox"/> Item
<input type="checkbox"/> There are written emergency protocols specific to the Mobile or Portable Unit, including appraisal of emergencies, initial treatment, availability of emergency equipment (including pediatric equipment/protocols as applicable), referral and/or transfer, as appropriate.
Emergency Equipment
<input type="checkbox"/> Emergency equipment and supplies, as required for the nature of services provided, are available and accessible (including pediatric equipment and supplies as applicable).
Contracts and Agreements
<input type="checkbox"/> The provider has signed/dated contracts and/or agreements delineating responsibility for services provided under arrangement, as applicable.
Patient Rights
<input type="checkbox"/> Patient Rights per MGL, c.111, s.70E applicable to the provider are extended to patients receiving services by a Mobile or Portable Unit and shall be posted in a Mobile Unit or provided to patients in writing by the Portable Unit provider.
Quality Assurance
<input type="checkbox"/> Quality Assurance indicators are identified which assure the services provided by the Mobile or Portable Unit, including contract services, are monitored through the provider's quality assurance program.
Mobile/ Portable Unit Staff
<input type="checkbox"/> At least one physician provides or supervises the provision of all services involving the practice of medicine, as applicable. <input type="checkbox"/> N/A
<input type="checkbox"/> There is at least one physician present whenever medical services are provided, or services are provided by a physician assistant or nurse practitioner pursuant to written protocols or guidelines in accordance with the regulations of the appropriate registration board. <input type="checkbox"/> N/A
<input type="checkbox"/> Medical staff credentials, appointments, and by-laws exist which indicate that staff providing medical services are appointed and abide by the by-laws of the Mobile or Portable Unit provider.
<input type="checkbox"/> There is an M.D. on-call coverage schedule to provide support to Mobile/Portable Unit staff as needed.
<input type="checkbox"/> Professional staff are appropriately licensed and receive the required supervision.
<input type="checkbox"/> There are written protocols which demonstrate oversight of Mobile or Portable services by the provider.
<input type="checkbox"/> There are written protocols for nurses practicing in the expanded role/physician assistants; nurse protocols are approved and are in conformance with Board of Registration in Nursing (see 244 CMR 4.00). <input type="checkbox"/> N/A
<input type="checkbox"/> There are written staff schedules ensuring adequate professional staff coverage for services offered.
Medical Record Services
<input type="checkbox"/> There are written protocols for the maintenance of medical records (e.g., storage, record retention, filing, access, security/confidentiality), including provisions for computerized medical records, as applicable, that are in conformance with state and federal requirements and the procedures of the parent facility/licensee.
<input type="checkbox"/> Records of patients receiving services from a Mobile or Portable Unit are maintained on the premises of the parent facility or at the registered address of record for exclusively mobile/portable providers.
<input type="checkbox"/> Records are not stored on a Mobile or Portable Unit or at host sites.



<input checked="" type="checkbox"/> Item
<input type="checkbox"/> The medical records of patients seen by a Mobile or Portable Unit are integrated or cross-referenced with existing clinic or hospital records (if applicable). <input type="checkbox"/> N/A
Medications <input type="checkbox"/> N/A
<input type="checkbox"/> Medications shall not be stored at any host site. <input type="checkbox"/> Medications shall not be stored overnight in a Mobile or Portable Unit. <input type="checkbox"/> There are written protocols which demonstrate oversight of medications or pharmaceutical services by the Mobile or Portable Unit provider/licensee. <input type="checkbox"/> Applicable registrations are obtained, as necessary, for the storage of drugs (including sample drugs), and/or provision of pharmacy services from: <ul style="list-style-type: none"> ▪ DPH Drug Control Program (for schedule II - VI drugs, i.e., <u>all stock prescription drugs</u>, including sample drugs); ▪ Federal Drug Enforcement Administration (DEA) registration (for schedule II - V drugs); <input type="checkbox"/> There are policies for the ordering, storage, dispensing, monitoring, control and accountability of all drugs, including documentation of disposal of outdated medications used in the provision of services by a Mobile or Portable Unit. <input type="checkbox"/> There are appropriately equipped medication preparation areas (e.g., work counter, sinks, refrigerator, locked drug storage) and appropriate lighting/ventilation on the Mobile Unit or at the host site, as applicable.
Radiological Services <input type="checkbox"/> N/A
<input type="checkbox"/> There are written protocols which demonstrate the provider's oversight of radiological services delivered by a Mobile or Portable Unit. <input type="checkbox"/> Applicable certificates, registrations and licenses are obtained for equipment. <input type="checkbox"/> There are policies in place for services, records, film storage and equipment maintenance.
Laboratory <input type="checkbox"/> N/A
<input type="checkbox"/> Laboratory examinations conducted in a Mobile Unit or at a Portable Unit host site shall be conducted in compliance with 105 CMR 180.000. <input type="checkbox"/> If specimen collection and testing are conducted by a Mobile or Portable Unit, the Mobile Unit, or Portable Unit host site, respectively, is equipped with appropriate space for such functions. <input type="checkbox"/> There are policies/procedures for all laboratory tests/services* provided by the Mobile or Portable Unit, whether provided in a vehicle or at a host site, <u>including but not limited to</u> policies and procedures for collection, labeling and transport of specimens, emergency procedures, safety precautions, monitoring of equipment and refrigerator temperatures. <p>* Note: Laboratory Tests includes ALL types of testing (e.g., dipstick, tablet, point-of-care, moderate/high complexity, cultures) performed on any body fluid (e.g., blood, serum, urine, feces).</p> <input type="checkbox"/> If limited testing is performed in a Mobile Unit, there is a Clinical Laboratories Improvement Act (CLIA) certificate for Laboratory Services, as applicable. <input type="checkbox"/> N/A <input type="checkbox"/> If tests beyond CLIA waived tests are performed in a Mobile Unit, <u>appropriate licensure and CLIA approvals and inspections are obtained, as applicable.</u> <input type="checkbox"/> N/A <input type="checkbox"/> There is a prescribing clinician <u>present</u> to provide orders for laboratory exams. <u>[DEFINE "PRESENT"]</u>



<input checked="" type="checkbox"/> Item	
Physical Environment	
<input type="checkbox"/>	The provider maintains the Mobile Unit in a safe and sanitary manner, or maintains agreements with the responsible party for the Portable Unit host site(s) that stipulate that the site(s) will be maintained in a safe and sanitary manner.
<input type="checkbox"/>	There are policies and procedures for provision of equipment and supplies to ensure safe and sanitary environment, either in a Mobile Unit or at a Portable Unit host site.
<input type="checkbox"/>	There are policies and procedures for managing snow and ice removal affecting access to the Mobile or Portable Unit or host site(s) (as applicable).
<input type="checkbox"/>	There are policies in place to ensure privacy (visual and sound) within a Mobile Unit or at a Portable Unit host site.
<input type="checkbox"/>	Facilities used for patients in a Mobile Unit or at a Portable Unit host site are accessible to handicapped individuals and comply with all federal, state and local requirements for handicapped accessibility.
Infection Control	
<input type="checkbox"/>	There are procedures in place to ensure that care provided by staff of a Mobile or Portable Unit is delivered in accordance with standards of practice for infection control, including provision of, or accessibility to, hand-washing facilities when indicated
<input type="checkbox"/>	There are written policies and procedures to ensure that patient care spaces and equipment are appropriately cleaned and sanitized before and after each patient encounter in a Mobile Unit or at a Portable Unit host site.
<input type="checkbox"/>	There are written protocols which demonstrate oversight of infection control practices provided by a Mobile or Portable Unit.
<input type="checkbox"/>	There are written protocols for the processing and disposal of infectious/physically dangerous medical/biological waste. [see State Sanitary Code, Chapter VIII; 105 CMR 480.000]
<input type="checkbox"/>	There are policies, procedures and protocols for linen storage/handling and housekeeping.
<input type="checkbox"/>	There are policies/procedures in place for identifying, reporting, controlling, and monitoring infections in patients/employees of the Mobile or Portable Unit.
Staff Training	
<input type="checkbox"/>	There is evidence of appropriate orientation/training of staff to policies and procedures, including fire safety, medical emergency care, etc., specific to the Mobile Unit or Portable Unit host sites.
<input type="checkbox"/>	There are personnel policies, job descriptions, staff schedules and credentials (e.g., application, license) for all staff categories.
Site Location	
<input type="checkbox"/>	Portable Unit services shall be provided in appropriate community host sites, as defined, and shall not include commercially rented office space rented by the licensee or the patient's home. <input type="checkbox"/> N/A
<input type="checkbox"/>	Mobile Units have policies and procedures regarding criteria for appropriate site locations for a Mobile Unit that include: <input type="checkbox"/> N/A <ul style="list-style-type: none"> requirements for solid, level parking surfaces and safeguards to prevent movement of the unit when parked minimum separation (30 ft) between the Mobile Unit and any building outside air intakes or any HVAC or generator exhaust (30 ft), and any unsprinklered building (20 ft) locating Unit to allow appropriate access to and exiting from Mobile Unit without interference with adjacent building exits or fire lanes [FGI 5.1-1.3.1.2(4)-(6)]



<input checked="" type="checkbox"/> Item
<ul style="list-style-type: none"> • safe patient drop-off zones and patient parking and parking for Unit carrier if applicable
Signage
<input type="checkbox"/> There is signage identifying the Mobile or Portable Unit, and if applicable, identifying an affiliation with a parent clinic or hospital, whether provided via a Mobile Unit or at a Portable Unit host site.
<input type="checkbox"/> Any signs, advertising, or other identification of a Mobile or Portable Unit clearly indicate that it is a mobile or portable health services program, and if applicable, indicates the service is sponsored by the parent facility.
<p>FGI Guidelines 1.3-3.1.1 Site signage to direct patients & visitors to parking areas & entrances (Primary Care Outpatient Centers checklist, OP2)</p>
<p>Hospital Outreach Program Policy, Rev. Oct. 1986, Jan. 1988, May 1990: "Any signs, advertising or other identification of an outreach program shall clearly indicate that it is an outreach program sponsored by the hospital."</p>
<p>105 CMR 140.560(J): Any signs, advertising or other identification of an outreach program shall clearly indicate that it is an outreach program sponsored by the clinic.</p>

Part III: MOBILE UNIT FUNCTIONAL AREA REQUIREMENTS

THE FOLLOWING ADDITIONAL REQUIREMENTS APPLY ONLY TO A MOBILE UNIT (van, trailer, RV, etc).

Please check each applicable item to indicate that the Mobile Unit complies with the following guidelines and requirements:

<input checked="" type="checkbox"/> Item
<input type="checkbox"/> Waiting and reception areas, with protection from the elements as needed, provision for drinking water, telephone and toilet access.
<input type="checkbox"/> Wireless communication provisions/capability.
<input type="checkbox"/> Records storage (during hours of operation).
<input type="checkbox"/> Exam/treatment room(s) sized to meet programmatic needs, designed to provide privacy (sight and sound), and equipped with exam lighting.
<input type="checkbox"/> Hand washing facilities with hot and cold running water are available for the following functional areas: <ul style="list-style-type: none"> <input type="checkbox"/> Nurses' area with medication prep/storage <input type="checkbox"/> Exam/treatment room(s) <input type="checkbox"/> Soiled holding area
<input type="checkbox"/> Storage cabinet(s) or closet for clean equipment, supplies and linen.
<input type="checkbox"/> Storage cabinet(s) or closet for soiled linen, trash and soiled equipment holding, separate from clean storage, with provisions for liquid waste disposal.
<input type="checkbox"/> Toilet room with hand washing facilities with hot and cold running water.



Item

- Heat, light, power and ventilation for all areas of the CMHP vehicle, including provisions for freeze protection and emergency power and lighting.
- Fire extinguishers.
- Support areas, as determined by the functional program, are provided within the CMHP vehicle, as applicable.
- The Mobile Unit vehicle is accessible to handicapped for entrance and egress (wheelchair, stretcher)
- Doors are furnished with safety or wire glass.
- Stairs include handrails on at least 1 side.
- Emergency exit lighting provided by battery.
- There are policies and procedures for maintenance of the Mobile Unit vehicle, including but not limited to cleaning, mechanical upkeep, registration and inspection.
- Records are maintained and are available for review for fire ratings of all structural materials and finishes and all testing and calibration records (air balancing, air filtration, sprinkler, biomedical equipment and electrical testing).