Potential Roles for Rural Ambulance Services in Vaccines and Monoclonal Antibody Infusions



Logical Partner







Illustration: Aïda Amer/Axios









Scope of Practice

 Before an EMS agency can administer the COVID-19 vaccine, must be authorized under applicable EMS scope of practice

NOTICES

DEPARTMENT OF HEALTH

Scope of Practice for Emergency Medical Service Providers

[50 Pa.B. 415] [Saturday, January 18, 2020]

Under 35 Pa.C.S. §§ 8101—8157 (relating to the Emergency Medical Services System Act) and the Department of Health's (Department) regulations in 28 Pa. Code §§ 1023.24(d)(1), 1023.25(d) (1), 1023.26(d)(1), 1023.27(d)(1), 1023.28(d), 1023.29(d) and 1023.30(e), the Department is publishing the scope of practice for emergency medical responders (EMR), emergency medical technicians (EMT), advanced emergency medical technicians (AEMT), paramedics (P), prehospital registered nurses (PHRN), prehospital physician extenders (PHPE) and prehospital physicians (PHP).

This is a State-by-State Issue

2 Examples...



Pennsylvania

- Current EMS scope of practice, published allows paramedics to administer approved immunization
- Many states approving EMTs

• Approved Medications Lists allows vaccines for: OAdvanced Life Support OCritical care transport OAir ambulance

| 103 Medications | Immunizations as published in the No No | No | Yes | | | | | | |
|-----------------|--|----|---------------|----|----|----|------------------|------------------|------------------|
| | Pennsylvania Bulletin by the Department |] | Immunizations | NO | NO | NO | YES ⁹ | YES ⁹ | YES ⁹ |



- Delegated EMS practice state
- Scope of practice and protocols are determined by agency's medical director



Illustration: Sarah Grillo/Axios



Purpose: To outline the procedure for the administration of the Pfizer and Moderna COVID-19 vaccine. These medicinal products have been given Emergency Use Authorization by the FDA for active immunization in individuals to prevent COVID-19 caused by the SARS-CoV-2 virus. This directive may be used by System providers who have completed an OMD-approved training program for COVID vaccine administration.

- Monitor patient for 15-minutes for signs and symptoms of adverse reaction
 - If signs and symptoms of adverse reaction, follow Allergic Reaction / Anaphylaxis protocol
- Ensure patients understand importance and time-frame for subsequent dose, if necessary

Cautions:

- · History of severe allergies or reactions to any medications, foods, vaccines, or latex
- · Immunocompromised or on a medication that affects the immune system
- Bleeding disorder or taking blood thinners
- Pregnancy or breastfeeding
- Has received a first dose of another COVID-19 Vaccine
 - Ensure same manufacturer as previous dose

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – October 29, 2020



https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

| PRODUCT | NEW/UPDATE | ADDITIONAL INFORMATION |
|---|------------|--|
| Vaccine Storage and Handling Toolkit | Update | An addendum with general COVID-19 vaccine storage, handling and transport information will be added, and the addendum will be updated as COVID-19 vaccine products are approved. A fully updated toolkit, incorporating COVID-19 information into the actual toolkit will not be issued until 2022. |
| COVID-19 training module | New | Under development is a web-based module. Topics will include storage/handing, vaccine indications, contraindications/precautions, administration, and documentation. It will not have CE and will be amended as new COVID-19 vaccine products are introduced. |
| Vaccine product summary sheets | New | Fact sheets with storage, handling, preparation, indications, contraindications/precautions, and administration will be developed for each vaccine |
| Additional immunization guidance materials | New | More extensive information related to storage, handling, preparation, administration, shipping, packaging, and transport will be provided as necessary (not all vaccines will need additional guidance) |
| Comprehensive table of vaccine products | New | A table of COVID-19 vaccine products with key information will be updated as vaccines are approved. |
| Beyond use dates and expiration date tracking tools | New | A resource will be provided to track BUD and expiration dates, for use early in vaccine distribution process. |



Illustration: Eniola Odetunde/Axios

Example: Texas Immunization Program Portal

Welcome to the Texas DSHS Immunization Program Portal

Here health care providers and pharmacies may register to be considered to receive COVID-19 vaccine.



Learn more about becoming a COVID-19 vaccine provider

Browser Compatibility Notice: For the best results using this application use the latest versions of Google Chrome or Microsoft Edge.

Please allow up to 14 days for processing of enrollment during this busy time.

Information to be Provided:

- Vaccine coordinator contact information
- Vaccine delivery times
- Vaccine storage capacity
- The patient profile of the population served



Other Requirements in Texas



- Administering and reporting information (ImmTrac2)
- List of responsible personnel such as the Chief Medical Officer or Medical Director
- Sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement





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Vaccines site 🕶

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Advanced Search

Vaccines & Immunizations

CDC > Vaccines and Immunizations Home > COVID-19 Vaccination > COVID-19 Vaccination Planning

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f Vaccines and Immunizations

Home

COVID-19 Vaccination Provider Support

For Parents

For Adults

For Pregnant Women

For Healthcare Professionals

COVID-19 Vaccination

For Healthcare Professionals

COVID-19 Vaccination Planning

COVID-19 Vaccination Program Operational Guidance

COVID-19 Vaccination Provider Support

Long-term Care Pharmacy Partnerships

Data and Reporting

All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into VaccineFinder. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into VaccineFinder. If you have questions about the process for your jurisdiction, please contact your jurisdiction's immunization program.

VaccineFinder Info

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., IIS) as soon as practicable and no later than 72 hours after administration.

Search

Enrolling in your jurisdiction/state-based IIS system Add the COVID-19 vaccine label to your VTrckS profile Get CDC's Comprehensive Vaccine Data Requirements III Get COVID-19 Vaccination reporting specifications III

https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html

CDC COVID-19 Vaccination Program Provider Agreement



Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) <u>and</u> chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement (Section A). CDC COVID-19 Vaccination Program Provider Profile Information (Section B) must be completed for each vaccination coefficient overed under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

| ORGANIZATION IDENTIFICATION | | | | |
|---|---|----------------------------|-----------------------------------|--|
| Organization's legal name: | | | | |
| Number of affiliated vaccination location | ns covered by | this agreement: | - | |
| Organization telephone number: | nization telephone number: Email (must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program): | | | |
| Organization address: | 1 | | | |
| - | | | | |
| | | | | |
| RESPONSIBLE OFFICERS | | | | |
| For the purposes of this agreement, in a | ddition to Or | ganization, Responsible | Officers named below will also be | |
| accountable for compliance with the cor | nditions speci | ified in this agreement. T | he individuals listed below must | |
| provide their signature after reviewing t | he agreemen | t requirements. | | |
| Chief Medical Officer (or Equivalent) Information | on | | | |
| Last name | First name | | Middle initial | |
| | | | | |
| Title | Licensure (s | tate and number) | | |
| Telephone number: | | Email: | | |
| | | | | |
| Address: | | | | |
| Chief Executive Officer (or Chief Fiduciary) Info | rmation | | | |
| Last name | First name | | Middle initial | |
| Telephone number: | Email: | | | |

| M | ay | vary | / by | / st | ate |
|---|----|------|------|------|-----|
| | | | | | |

CDC COVID-19 Vaccination Program Provider Agreement



Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) <u>and</u> chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination Location covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

| ORGANIZATION IDENTIFICATION | |
|---------------------------------------|---|
| Organization's legal name: | |
| Number of affiliated vaccination loca | tions covered by this agreement: |
| Organization telephone number: | Email (must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program): |
| Organization address: | |

Address:

CDC COVID-19 Vaccination Program Provider Agreement

AGREEMENT REQUIREMENTS

I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

Organization must administer COVID-19 Vaccine in accordance with all requirements and

recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).¹
 Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.²

2. Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.²

Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.

Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides

- without cost to Organization. Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay
- 4. COVID-19 Vaccine administration fees.

| 5. | Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine | | | | | |
|----|--|--|--|--|--|--|
| | recipient, the adult caregiver accompanying the recipient, or other legal representative. | | | | | |
| 6. | Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance | | | | | |
| | for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. ³ | | | | | |
| 7. | Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit⁴, which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit⁴; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions; | | | | | |

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

- ¹ <u>https://www.cdc.gov/vaccines/hcp/acip-recs/index.html</u>
- ² <u>https://www.cdc.gov/vaccines/programs/iis/index.html</u>
- ³ https://www.cdc.gov/vaccines/pandemic-guidance/index.html
- ⁴ https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

9/14/2020

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Scenario

2 Currently Enrolled in Medicare as Other Provider Type but not Eligible to Bill for Administering Vaccines (e.g. DME Supplier, Ambulance, IDTF,

....

2a Enroll in Medicare as Mass Immunizer to Roster Bill







Contact the MAC hotline that serves your geographic area



- Legal business name
- NPI
- TIN
- State license number, if applicable
- Practice location information
- Contact information (phone number, email address)



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MAC screens the provider over the phone and establishes temporary Medicare billing privileges. Provider receives notification within 24 hours.



Submit vaccination claims to Medicare

Roster Billing

Must administer the same type of vaccine per roster claim to 5 or more people on the same date. Submit claim to specific <u>MAC</u> jurisdictions based on location.



Electronic Claims: Contact your Vendor/Clearinghouse or download free PC ACE billing software and electronically submit roster claims to your MAC.

Paper Claims: Use <u>Health Insurance Claim</u> Form (CMS-1500)

a. <u>Contact your MAC</u> for the roster form

https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots

| Institutional | Non-Institutional | Durable Medical Equipment (DME) | |
|--|--|--|--|
| Outpatient Physical Therapy Occupational Therapy Speech Pathology Services Histocompatibility Laboratory Religious Non-Medical Health Care Institution | Independent Clinical Laboratory Ambulance Service Supplier Independent Diagnostic Testing Facility Intensive Cardiac Rehabilitation Supplier Mammography Center Medicare Diabetes Prevention Program Suppliers Portable X-ray Supplier Radiation Therapy Center Opioid Treatment Program Organ Procurement Organization Home Infusion Therapy Supplier | Durable Medical Equipment Supplier Pharmacy (enrolled as DME supplier | |

https://www.cms.gov/covidvax-provider

COVID-19 MAC Webpages and Hotlines

Only contact the COVID-19 Hotline for the Medicare Administrative Contractor (MAC) that serves your geographic area.

| Medicare Administrative Contractor (links to webpages) | States and Territories per MAC Jurisdiction | Toll-free Hotline Telephone Number | Hotline Hours of Operation, Monday – Friday |
|---|---|---------------------------------------|--|
| CGS Administrators, LLC (CGS) | Part A/B: J15: Kentucky, Ohio | 1-855-769-9920 | 7:00 am – 4:00 pm CT |
| | Home Health & Hospice: J15: Colorado, Delaware, District of Columbia, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, Wyoming | | |
| First Coast Service Options Inc. (FCSO) | JN: Florida, Puerto Rico, U.S. Virgin Islands | 1-855-247-8428 | 8:30 am – 4:00 pm ET |

Payment Allowances and Effective Dates for COVID-19 Vaccines and their Administration during the Public Health Emergency:

| Code | CPT Short Descriptor | Labeler Name | Vaccine/Procedure Name | Payment Allowance | Effective Dates |
|-------|---------------------------------|-----------------|--|----------------------|---------------------|
| 91300 | SARSCOV2 VAC 30MCG/0.3ML IM | Pfizer | Pfizer-Biontech Covid-19 Vaccine | \$0.010* | xx/xx/xxxx – TBD |
| 0001A | ADM SARSCOV2 30MCG/0.3ML 1ST | Pfizer | Pfizer-Biontech Covid-19 Vaccine Administration – First Dose | \$16.940** | xx/xx/xxxx – TBD |
| 0002A | ADM SARSCOV2 30MCG/0.3ML 2ND | Pfizer | Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose | \$28.390** | xx/xx/xxxx – TBD |
| 91301 | SARSCOV2 VAC 100MCG/0.5ML IM | Moderna | Moderna Covid-19 Vaccine | \$0.010* | xx/xx/xxxx – TBD |
| 0011A | ADM SARSCOV2 100MCG/0.5ML1ST | Moderna | Moderna Covid-19 Vaccine Administration – First Dose | \$16.940** | xx/xx/xxxx – TBD |
| 0012A | ADM SARSCOV2 100MCG/0.5ML2ND | Moderna | Moderna Covid-19 Vaccine Administration – Second Dose | \$28.390** | xx/xx/xxxx – TBD |

* Since we anticipate that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free.

** These rates will also be geographically adjusted for many providers. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.

| NO | VITAS | CENTERS FOR MEDICARE & MEDICAID SERVICES |
|--|--|---|
| | | 12/7/2020 |
| METROPO 2900 ALTA FT WORTH | | |
| Attention: M | IATT ZAVADSKY | |
| Reference: | National Provider Identifier (NPI): Provider Transaction Access Number (PTAN) | |
| Dear METR | OPOLITAN AREA EMS AUTHORITY: | |
| pursuant to t emergencies phone call or immunizatio | written confirmation that you have been granted tempor the CMS waiver of certain enrollment and screening requ associated with COVID-19. These temporary billing privileges and n DECEMBER 7, 2020. Temporary billing privileges and n services. Listed above are your National Provider Idea Access Number (PTAN). | airements during the national ivileges are being established per a re being established to provide mass |

Eli Lilly says monoclonal antibody cocktail cuts hospitalizations by 70% for high-risk COVID-19 patients Karen Weintraub, Jan. 26, 2021

While vaccines may help slow the COVID-19 pandemic over the next months, drug company Eli Lilly announced Tuesday that its treatments can help save lives in the meantime.

The company's drug bamlanivimab was authorized by the U.S. Food and Drug Administration late last year and has been used by 125,000 high-risk patients nationwide based on early-stage data suggesting it could be effective.

The drug is a monoclonal antibody, meaning it mimics one of the natural antibodies the immune system uses to fight off the virus.

Former President Donald Trump as well as former New Jersey Gov. Chris Christie and former New York City Mayor Rudy Giuliani <u>all received monoclonal antibodies</u> shortly after they were diagnosed with COVID-19.

In a large, late-stage study the company unveiled Tuesday, bamlanivimab combined with another monoclonal antibody, etesevimab, was found to be extremely effective in high-risk patients diagnosed with COVID-19.



https://www.usatoday.com/story/news/health/2021/01/26/eli-lilly-monoclonal-antibodies-high-risk-covid-19patients-coronavirus/4263087001/

FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB

AUTHORIZED USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- Bamlanivimab is not authorized for use in patients:
 - o who are hospitalized due to COVID-19, OR
 - o who require oxygen therapy due to COVID-19, OR
 - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.



Payment Allowances and Effective Dates for COVID-19 Monoclonal Antibodies and their Administration during the Public Health Emergency:

| Code | CPT Short Descriptor | Labeler Name | Vaccine/Procedure Name | Payment Allowance | Effective Dates |
|-------|------------------------------------|-----------------|--|----------------------|---------------------|
| Q0239 | bamlanivimab- xxxx | Eli Lilly | Injection, bamlanivimab, 700 mg | \$0.010* | 11/10/2020 – TBD |
| M0239 | bamlanivimab- xxxx infusion | Eli Lilly | Intravenous infusion, bamlanivimab- xxxx, includes infusion and post administration monitoring | \$309.600*** | 11/10/2020 – TBD |
| Q0243 | casirivimab and imdevimab | Regeneron | Injection, casirivimab and imdevimab, 2400 mg | \$0.010* | 11/21/2020 – TBD |
| M0243 | casirivi and imdevi infusion | Regeneron | intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring | \$309.600*** | 11/21/2020 – TBD |

* Since we anticipate that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free.

*** Medicare will pay a rate of \$309.60 for many providers. These rates will also be geographically adjusted for many providers. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.

Is your agency participating in administering COVID vaccines to the public? If Yes, are you staffing other clinics, or doing your own?





What has been your #1 "Ah Ha" moment regarding participating in COVID vaccine administration?

What advice would you give to other EMS agencies considering getting involved in vaccine administration?

- Registration and scheduling have to be very organized and clearly communicated to the public
- Bureaucratic road blocks
- Prove our value, get involved
- It is imperative to have an understanding of how much vaccine is available, in order to accurately and adequately staff the clinic. It is also important to ensure that minimum staffing is achieved to reduce back-ups and increased wait times
- lack of prehospital involvement in the planning of vaccine administration, overlooking a huge resource but training pharmacy techs instead
- Train with DPH or hospital systems to learn how to effectively manage large crowds with minimal staffing, immunization documentation, CMS roster billing
- Being prepared for the data entry and logistics of hosting the clinics ahead of time. The more work is done prior to hosting a clinic, the better and smoother the clinic runs.
- Work closely with your Local Public Health officials to work and plan for EMS involvement in vaccine administration
- Stay focused on making a positive and compassionate impression with the public
- It is positive interaction that can lead to increased public confidence in future areas

CMS allows ambulance agencies to be reimbursed for vaccine administration.

If you are doing your own clinics, are you planning to bill, or already billing for the vaccine administration?



Is your agency participating in *monoclonal antibody* (mAb) infusions for the public?



If Yes, are you staffing other infusion centers, or doing your own?



What has been your #1 "Ah Ha" moment regarding participating in mAb infusions?

What advice would you give to other EMS agencies considering getting involved in mAb infusions?

- Be aware of the State's ordering process
- It is an issue of resource management and patient flow
- We do the mAb infusion in place at LTC and LTAC so we don't use resources to move them for the infusion
- We are trying to assist filling gaps within the local health care systems because of lack of capacity to meet the growing demand during this pandemic. There were challenges with scope of practice when working in non-urgent areas.

Service area type

Rural and Frontier Breakdown



| Yes | 62% |
|-----|-----|
| No | 38% |

Are you staffing other clinics, or doing your own??

| Doing our Own | 44% |
|-----------------|-----|
| Staffing Others | 22% |
| Both | 11% |
| Other | 22% |

Tips:

- Know who your Community partners are in assisting with the vaccination program. Your partners vary from one county to another.
- Close collaboration with Public Health has been instrumental
- Planning for employee sick time due to side effects
- Vaccine is coming in very slow to our community.









Other Roles Discussed w/Flex Participants

• COVID Testing

o On-site and in-home

• Alternate dispositions for potential COVID+ patients

Treatment in Place
Alternate Destinations

Telemedicine facilitation

On 9-1-1 calls or pre-scheduled
 Station-Based clinics

• Follow-up care after discharge

o Reduce Length of Stay/Observation Admissions

• Subscription service

o Basic + enhanced services on demand



