TECHNICAL PRESCRIPTIONS

AMBULATORY PATIENTS' DRUG ADHERENCE SERVICE – APDAS: Expedient no. 11 HMS/2017

I. OBJECT

As stated in clause 1.1 of the PCAP, the purpose of this tender is to VALIDATE a comprehensive service for the promotion and follow-up of ADHERENCE for elderly patients receiving therapeutic care from the "Unit for the Therapeutic-External Patients" (UAF- PEX) of "Miguel Servet University Hospital of Zaragoza", through the application of innovative uses of available technologies. The aforementioned service has been called "AMBULATORY PATIENTS' DRUG ADHERENCE SERVICE" (hereinafter SAMPA from its initials in Spanish).

The objective is the complete traceability from the care process', the patient's and the drug´s point of view. In the area of external patients that includes from prescription to storage and dispensation, efficiency and minimization of non-care times are sought. To this end, technologies that are available, as well as new ones, will be used to ensure adherence monitoring and permanent information channels about the treatment, adverse effects and possible patient interactions (non-attendance systems: website or mobile app).

The ultimate purpose of the contract is to improve patients' health outcomes efficiently (at the lowest possible cost and best quality) by automating and redesigning processes, as well as using digital technologies for the empowerment of patients and to ensure maximum availability in the drug delivery.

II. FINANCING

This tender is partly funded as part of the STOPandGO project. This is a PPI pilot project Co-funded by the ICT Policy Support Program (PSP ICT) of the European Union (CIP ICT PS2007-2013), Grant Agreement No. 621013.Innovation.

III. REQUIREMENTS AND TECHNICAL SPECIFICATIONS

This sheet contains the specifications by conceptual and logical phases of the therapeutic procedure and marks functional specifications and expected requirements in each of the phases. Furthermore, a timeline for the implementation is proposed as well as a series of items that will determine the correct progress of the project. The viability commitments written in the contract will also be established.

The following **minimum requirements** apply to all phases:

1) **Sustainability and responsibilities:**
   a. All processes will be carried out based on the concept of electronic administration, starting from the principle of single act and absence, or minimization, of the role in the transactions.
   b. Solutions based on freeware and platform independent software will be valued, if licenses of any type are required, all will be unlimited and be borne by the supplier during the project life cycle.
   c. Consistency and integration will be required with all existing systems in the organization. The supplier will provide the definition and documentation of

integration procedures on HL7 and other standards that are specified for integration with any future implementation. All this without added cost for the HUMS

d. All supplies, works, structural modifications and other adaptations must comply with the sustainability and energy efficiency regulations in place at the time of receipt, as well as all the necessary requirements to ensure the integration of patients and workers with disabilities, according to the regulations in use at the time of receipt.

2) Implementation schedule:

a. The initial phase will include a complete revision of the circuits and operating rules of the whole area, as well as a consensual redesign of circuits and dispositions of the different components of the system
b. An implementation schedule will be demanded in the offers, with references to milestones and deliverables. (See timeline references, section V of this document)
c. The deadline for the system to be fully functional is March 2018
d. Repeated breach of deadlines, or lack of functionality, will result in the penalties and deductions provided for in the PCAP

3) Adequacy of spaces:

The contractor will assume any structural modifications and adaptations of spaces necessary for the correct functioning of all phases related to the drug-therapeutic management. Redesigning of spaces and placement of all the necessary devices for the correct functioning, including any minor civil construction work needed will also be covered by the contractor.

In this phase, special emphasis will be placed logical management of the outpatient dispensing area. More specifically:

a. Dispensation based on knowledge, distinction of positions by content
b. Direct assisted dispensing
c. All structural modifications and adaptations of spaces will comply with the current legislation on accessibility for people with reduced mobility. Any changes will comply with the Occupational Hazard Prevention Service guidelines, as well as energy efficiency and sustainability guidelines.
d. Sizing in function of attendance.
e. Adaptation of spaces according to the models of appointment management and patients' comfort.

4) Functional decomposition:

The complete project reference scheme is shown in figure 1

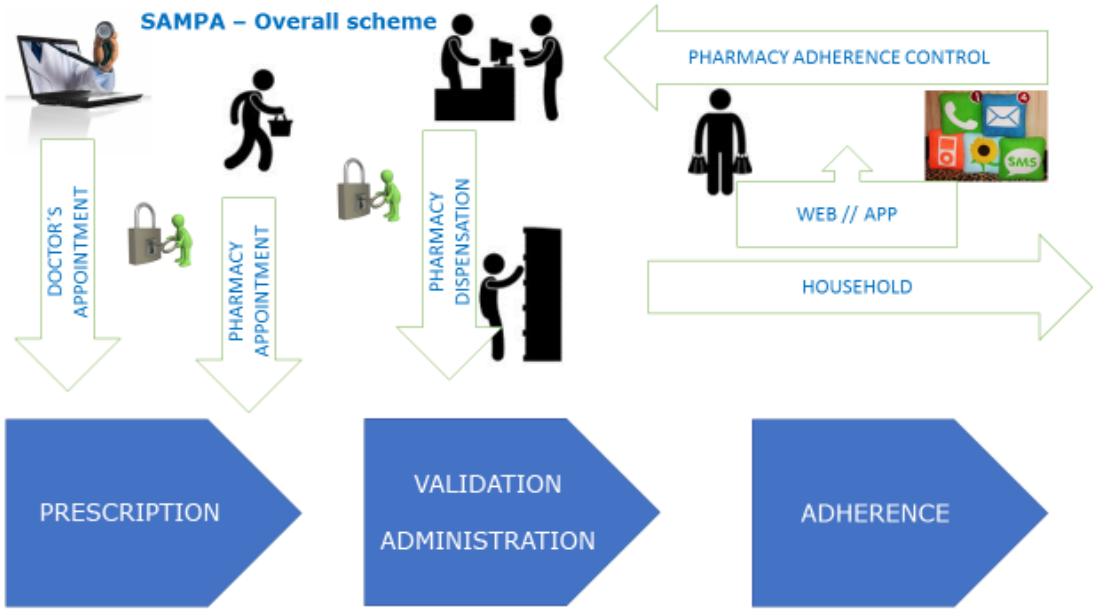

Figure 1

The model's coherence and the main innovation intended to be implemented are the result of an integral, conceptual vision: from PRESCRIPTION, involving the management of care and validation to DISPENSATION, to be performed in the pharmacy, to reach ADHERENCE, in the household of an elderly patient.

Thus, the system itself is integrated and coherent. It allows monitoring from and to any point, empowering all agents, those being: patients, prescribers, pharmacists, drugs, people and intermediate devices.

In short, it is a matter of offering an integral service to patients treated in the Outpatient Unit of the Pharmacy Service at the Miguel Servet University Hospital through the application of new technologies, which will imply a change of culture in the organization and will favor patient's empowerment.

In any case, the following functional requirements must be respected:

5) Information systems

a. All systems developed will comply with the current regulations regarding security and information protection, as well as the applicable technical standards in relation to the usability and accessibility of the software.
b. Friendly user interface, integrating the corporate image elements of the Aragonese Health Service.
c. Modular and flexible development, allowing independent operation of each component to facilitate both the implementation and evolution of the system.
d. Features for personalization by user and profile.
e. Scalable system that ensures the optimal performance of all the functionalities in a 24x7 system taking into account the number of concurrent users and the estimated volume of information.

f. Inclusion of tools that facilitate the exploitation of the information managed by user administrators.
g. Compliance with technical standards for general interoperability (service orientation), interoperability in the healthcare environment (HL7 and IHE), according to the integration standards agreed with the Integration Office of the Aragonese Health Service.

i. Technological independence.

a. The operating system independence of both the server and the clients (personal computers and mobile devices).
b. The independence of the database manager.
c. The independence of browsers.
d. The independence of the application server.

ii. Infrastructure / equipment

a. The equipment that is provided for the implementation of the project (physical or virtual servers, storage, database manager, application servers and client posts, if applicable) will be integrated into the TCP / IP data network of the Aragonese Health and In their systems infrastructure.
b. Interoperability must be preserved.

IV. FUNCTIONALITY NEEDS

The functionalities must meet the following requirements:

Attached Figure 2, to provide the general considerations

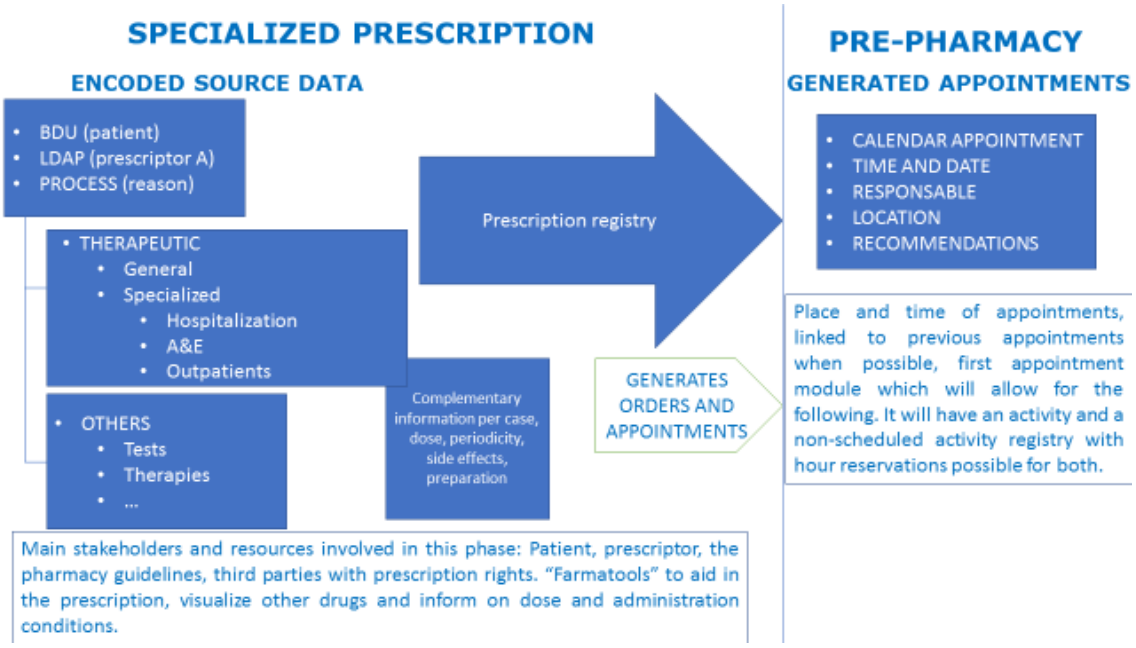

Figure 2

I. PRESCRIPTION

The solution proposed should cover all the needs of pharmacological and non-pharmacological prescription requirements of outpatients (including dietary measures, lifestyle, etc.).

It must be multi-user and multiplatform, without limitation of concurrent users. All integrated within the data protection regulations required by the LOPD and European standards.

The **electronic prescription platform must incorporate** information on the patient, prescriber and prescription in the same scenario, including at least:

1) Patient data (demographic variables, anthropometric characteristics, allergies and intolerances and clinical data of interest)
2) Information of the prescribing physician (identification, service)
3) Prescription: drug, route, dose, dosage regimen, duration, indication or reason for prescription.

As **guidance, but not exclusively**, the main integration scenarios that the system must support are listed below:

1) Authentication system (corporate AD) and authorization of professionals (GUIA) through development of connectors (web-based service or database) that allow management of users and roles to be assigned in the application.
2) Corporate Identity and Patient Management (Corporate Master Patient Index), AD messaging.
3) Centralized system of structure management and standardization of services, ADT messaging.
4) Centralized system of structure management and standardization of services, MFN messaging for the maintenance of catalogs.
5) Hospital Pharmacy Management System (Farmatools a product of the company Dominion) with which the service provided must interact in its modules of Guide Pharmaco-therapeutic, prescription, dispensing and management of adherence. This integration is considered key to the success of the implementation of the project, therefore, the service provider must include the costs for the analysis and implementation of the integration scenarios. At least the HL7 messaging exchange for technical and medication teachers (MFN), prescribing, dispensing and administration (OMP, RDS, RDS etc.) and for the management of stocks will be considered.
6) Corporate module of discharge management (SIU messaging)
7) Integration with HCE platform and Pharmacotherapeutic History of the patient.
8) In addition, consideration should be given to integration with other systems within the Health Pharmacy information systems evolution project.

The details regarding the implementation of the previous scenarios will be defined jointly with the successful tenderer throughout the development of the system.

a. System Content

The **proposed system should**, in any case:

1) Incorporate the necessary aids to support the clinical decision. Amongst those: adjustment in special situations, maximum dose, protocols, interactions, allergies, etc.
2) Allow the exchange of permanent and immediate information between the different professionals who attend the patient and will facilitate the registration and exploitation of the information of the problems that can arise with the use of the medicines: allergies, errors, URM, contraindication, etc.
3) Generate activity reports and statistics, as well as activity forecast reports.

b. Citation and pharmaceutical visit

The Service offered here will include a Service of appointments for care in the Pharmacy Service that may be generated at the time of prescription of a drug, from the medical consultation or from the Pharmacy Service itself at the time of the Dispensing.

II. **DISPENSATION** (pharmaceutical validation and administration)

Attached in Figure 3 is the conceptual schematic

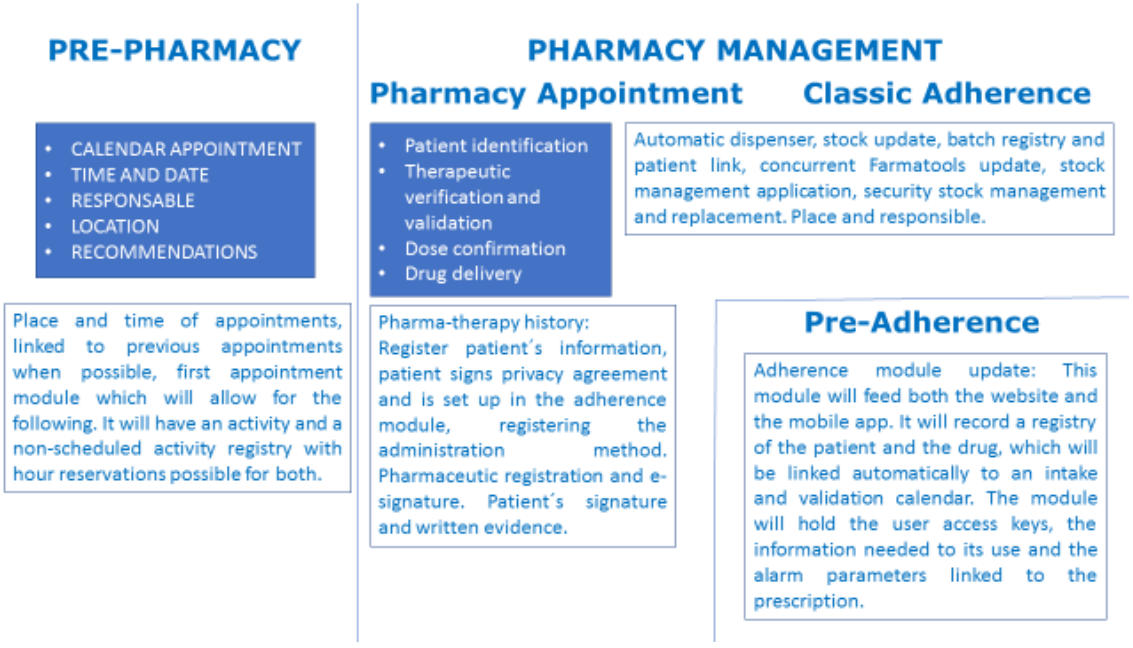

Figure 3

The proposed Service should cover all the functionalities necessary for the monitoring of drugs in all scenarios provided for outpatients. It will include automated storage to ensure stock management and automated expiration and maintenance of adequate storage conditions to ensure the quality of medicines.

1) It will allow the automatic entry of the drug with unique identification of the drug through bar code reading and/or data matrix, real-time inventory minimizing discrepancies between the theoretical and actual stock (<0.1%), The elimination of location errors and the optimization of storage when using a chaotic storage system.
2) This system will be interconnected with the stock management system and the outpatient dispensing module available in the Pharmacy Service and with the hospital temperature control systems.
3) The Service will include the provision of the equipment, technology and information system necessary for the proper management of the indicated system, as well as the necessary advice and support for the start-up and maintenance.
4) It will also include the structural modifications and / or adaptations necessary for the commissioning of the Service offered, as well as the control systems to guarantee adequate humidity and temperature conditions for the different presentations of the medicines. Guaranteeing the maintenance of the cold chain when this is necessary.
5) For this purpose, storage of medicaments at room temperature and storage spaces for thermal-sensitive drugs, with capacity in accordance with the requirements of HUMS. Storage requirements of 14,000 containers, 65% of them at room temperature and 35% thermal-sensitive drugs.
6) Module of automatic loading, to be implemented with a hopper or similar element, in which the packaging is deposited in commercial format of the different medicines.
7) Facilitate the pharmaceutical presentation in the place of care, maintaining the principle of single act and favoring the optimization of the time of attention, prioritizing information and individualized attention to delivery. Delivery is to be automatized with more than 85% of the drugs supplied in an automated way.
8) Automatic medication dispenser that allows the direct dispensing assisted through a system of tutelage by image and / or sound outside the opening hours of the Pharmacy Service, in selected patients. It will allow dispensing receiver validation univocally and allocation
9) The system offered will comply with the occupational safety and health regulations on ambient temperature / thermolabile conditions of noise, thermal dissipation, vibrations, electrical safety, etc. And it will allow the adequate preservation of the conditioning of the medicines, ensuring the integrity of the medication (the number of damaged containers will not exceed 0.001%).
10) The Service will minimize immobilized stock, improve stock adjustment to patient needs, and increase patient care time.
11) The number of containers dispensed at the time will be over 200 with the waiting time from the request to the reception of less than 30 seconds.
12) The Service will incorporate a system of identification, registration and validation of the dispensing receiver, both for direct dispensing and through the remote dispensing system.
13) The system will ensure the total traceability of the dispensing of medicines and will have an alternative plan of action in emergency situations.
14) The system must comply with all safety standards for both the manipulator and the drug, as well as the patient. Furthermore, it has to meet the criteria of accessibility and usability.

III. ADHERENCE: (patient empowerment and reinforcement of therapeutic support)

Attached Figure 4 with the conceptual description

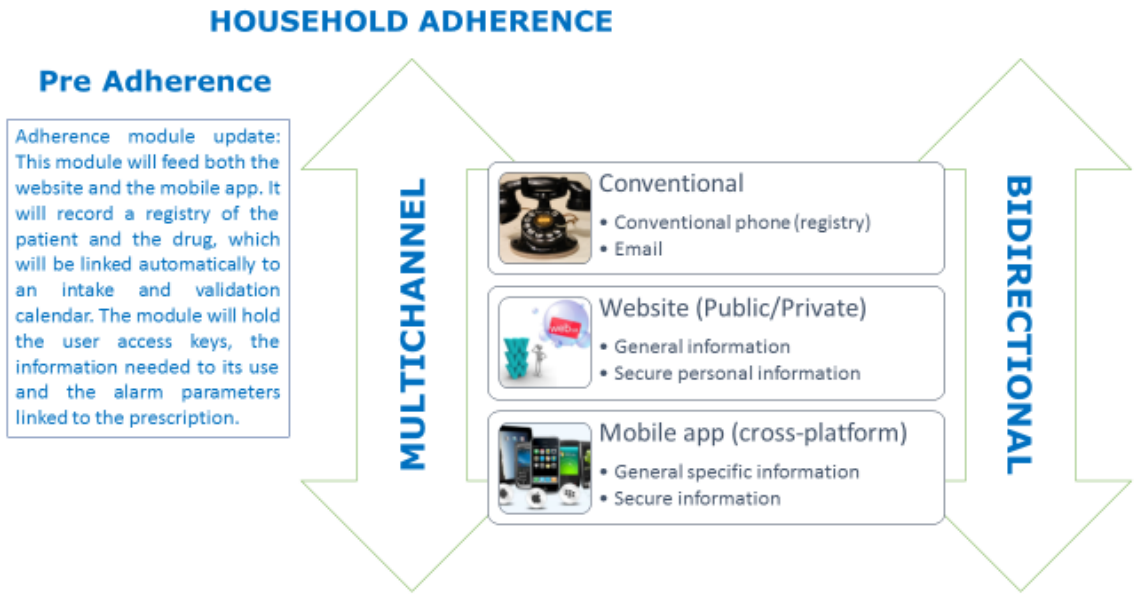

Figure 4

1) The Service will include a patient information and training system on its pathology and treatment and a double adherence monitoring system.
2) This system will allow the assessment of the agreement between prescription and dispensing to detect the primary non-compliance.
3) It will also provide the assessment of adherence in real time through the personal registration by the patient of self-administered medication.
4) It will have a system of alerts in the absence of adherence and will allow the stratification of the risk of non-adherence of the patient.
5) The service will include the development of:
   a. A Web Portal with a public and a private part.
   b. The Public will collect general drug-therapeutical information, accessibility, norms of operation of the Unit, notifications of interest of interest to any user in treatment.
   c. A private area, managed by the incorporation to the project, will formalize a co-responsibility contract with the user, voluntary and that assures a responsible use. Once delivered the keys the user will enter a private area with personalized information, possibility of management and registration of their adherence and ability to contact directly with their assigned pharmacist, as well as other information of interest (pharmaco-therapeutic history, registration of incidents, Frequently Asked Questions, Next Appointment, Outpatient Information, and Medication Maintenance Conditions)
   d. A multiplatform APP, which allows the patient to participate as a manager of their illness, validate their medication intake, control their status, their schedule and their adherence and enjoy tools for their activation. As in the previous case the patient should adhere to the project.

- The ease of use and friendliness of the solution will be assessed according to the current standards of this type of solution.
- Applications will have periodic updates and improvements based on user feedback and contributions received, at least quarterly.

e. You must allow registration of any type of medication, including phytotherapy.
f. The repository shall comply with all the requirements of the LOPD for the use of individual patient data.
g. These tools will allow professionals of the Pharmacy service and the health center to have a tool for monitoring and monitoring adherence and therapeutic compliance
h. They will have personalized alarms for monitoring from the Pharmacy Service and the possibility of intervention depending on the different solutions. The intuitive and easy tracking system for each professional so that, with an overall look, by a system of visual alerts can know in each moment the situation of patients included in the adherence program.
i. It shall be considered as a minimum;
    - 100% of the patients will enter the primary adherence program
    - 50% will be included in the private area of the web information repository.
    - 30% of the patients will enter the secondary adherence program at home

V. SCHEDULE AND MONITORING OF THE PROJECT

A Project Committee will be set up to monitor the project to be established by the HUMS at the beginning of the contract. This Committee shall be attended by a person from the awarded company capable of supervising the contract and the services.

Milestones of reference to be developed in the offer:

1) Field study and process re-engineering, one month from the formalization of the contract, with elaboration of a consensual document of action
2) Realization of structural adaptation and placement of work devices in the area of External Pharmacy Patients, two months between minor civil works and placement of devices and configuration of connections and total operability.
3) In concurrent and simultaneous development:
    a. Prescription: Consensus on the design, preparation of technical solutions, customization of the solution and implementation three months from the signing of the consensus document, in no case will exceed four months from the award, will be appointed a functional and technical person, Of each of the parties.
    b. Citation together to the functionality of prescription.
    c. Dispensing, primary adhesion and traceability: At the moment in which the item 2 described above ends, at the latest in the third month of the award
4) Adhesion Phase
    a. Implementation of Web Portal
        i. Public part, linked to the project and designed to update content from the Pharmacy Service, in the first three months.

ii. Private part for incorporation of patients
    1. It will be performed by phases and profiles of patients at a rate of one group of patients per month as of the fifth month of adjudication. Functional managers will also be defined.

b. APP Solution
    i. Implementation again by therapeutic profiles starting design from day zero like the previous ones, first prototype within the first six months, progressive incorporation of patients, closure and evaluation in February 2018.

At the end of each of the phases or milestones, the developed systems will be operating in production environment. According to the planning of the project, provision should be made for the provision of corrective and evolutionary support from the partial or total implementation of each of the subsystems that make up the service according to the requirements specified in section IV of this document.

A contingency plan should be available, which will consider alternative ways of functioning in the event of any eventuality that limits the availability of the system.

VI. RECEPTION, SUPPORT AND CORRECTIVE MAINTENANCE

1) Technology transfer.

All equipment will be delivered with all necessary documentation for proper maintenance and use. The winning bidder must provide at least two copies of the Operation and Maintenance Manuals in Spanish.

During the execution of the service, the successful tenderer undertakes at all times to provide the persons designated by the Aragonese Health Service with the information and documentation that they request in order to have knowledge of the circumstances in which the work is carried out and the results of the same.

In addition, the successful tenderer undertakes to adequately document, in the formats standardized by the Aragonese Health Service, the work developed, actions and modifications of the different information systems.

2) Support and maintenance services.

According to the project planning, the companies will detail in their technical offer the proposed model for the provision of corrective and evolutionary support services, starting from the partial or total implementation of each of the subsystems that make up the service, which must comply with the following requirements.

A. Corrective support will include:

- The monitoring of the correct operation of the platform, in coordination with the operations technicians and systems of the Aragonese Health Service.
- Development of technical documentation and descriptive procedures to serve as a basis for this collaboration.

- Management of Incidents and Problems from its appearance to its closure and validation.
- Development of procedures for opening and tracking incidents.
- Procedures and execution of version update of the applications, with their corresponding regression plans. The execution windows of these updates will be agreed based on an analysis of effort and impact.
- Development of operating procedures and resolution of incidents for the transfer of knowledge to the technicians of the Aragonese Health Service.
- Disaster recovery procedures and critical actions on systems.

B. Coverages:

- The support service coverage will be in 24x7 hours, and means of remote connection to the systems may be used. The Support Service Will have the following ways of contact for opening incidents and consultations:
  - Telephone. Single contact telephone, available 24 hours a day, 7 days a week and every day of the year.
  - Email

The criticality levels for the classification of incidents will be the following:

- **Level 1. Critical**. System out of service or critical exploitation.
- **Level 2. Severe**. Those that significantly affect the operation of the units.
- **Level 3. Light**. The rest of incidents that by their nature do not require an immediate resolution, or those that do not severely affect the operation and performance of the units.

At a minimum, corrective support services will be provided according to the following levels of service. (Penalties for non-compliance will be collected in the PCAP)

	Maximum response time	*Maximum resolution time*
N1	30 minutes	4 hours
N2	30 minutes	8 hours
N3	One business day	2 business days

3) Evolutionary Service Support and Technological Solutions.

The contractor must provide for the execution of evolutionary maintenance services throughout the contract for each of the subsystems implemented, the modules for integration and exploitation of information and additional training services. An application procedure, scope determination and change management will be provided for this evolutionary maintenance.