



Health Care Solutions

AFI Health Care Solutions srl was founded in the 2014 as a spin-off of AFI snc, Society operative since the 2001 in the providing of professional figures and experts, such as doctors, practical nurses, physiotherapists, speech therapists, psychologists and support staff. AFI Health Care Solutions offers a service of technique-nursing assistance dedicated to the companies operating in the healthcare field and that requires the use of strumental, professional, integrated and coordinated sources, following a model to guarantee an adequate attention to the patient. AFI Healthcare Solutions is described as a qualified partner of Pharmaceutical Industries, C.R.O., Electromedical and Biomedical Companies, Societies of healthcare services management and Associations of Patients.

OUR METHOD

AFI Healthcare Solutions is composed by a team of professionals of the health and pharmaceutical industry able to work with the best tested methods providing innovative solutions:

- ANALYSIS – information gathering
- CONCEPT – identification of need
- DEVELOPMENT – elaboration of the activities and tools and plan of action
- PRODUCTION – emission of the activities and quality monitoring
- SUMMARY – control of the goals achieved and analysis of the quality indicators

OUR SERVICES AFI ONLINE:

Toll-free number with answering service 24/7 active. Web-site for the request of the material of support. Implementation of the operative software for the services management. Management of our emergencies dedicates warehouse for the medical devices and their delivery through a qualified courier. Pharmaceutical and external warehouse certified for stocking and delivering the consumer product. Patients transport with protected cars and ambulance from their house to the dedicated building for the hospital therapies. Organisation of training activities and consultancy D.Lgs 81/2008. Organisation of courses for the medical training in order to guarantee the right healthcare and prevention of the diseases. Constant training of the medical staff for the creation and updating of organisational models for the management (ex D.Lgs 231/01).

TECHINICAL HELPLINE SERVICE WITH A SPECIALISED MULTILINGUAL STAFF:

Technical helpline service with toll-free number managed by a specialised multilingual staff (HCSI - Health Care Services International). Correct use of the devices, management of the complaints. Information for the sostitution and the correct disposal of the devices – management of the expiry dates. Toll-free number dedicated to the coordination of other agencies' toll-free numbers through an operations centre for the support and technical assistance directed to the patients. Planification, coordination and management of the helpline services and the emergencies for Italian citizens and foreign residents based in Italy who need an immediate medical assistance.

TECHINICAL NURSING ASSISTANCE AT HOME AND WITH MULTILINGUAL HELPLINE:

- Planification of the visits both at home and at a hospital unit. Equal distribution of the nurses all over the national territory.
- Constant interface with the staff of the dedicated helpline.
- Training for the use of the devices and for the resolution of any problem regarding the

- administrating of products.
- Beginning of the therapies, chronic therapies, measurement of the vital signs, follow up visits and management of the complaints.
- Modification of the doses with both the visit at home and the helpline assistance (with the authorisation of the attending doctor).
- Warning of the adverse events unasked from the specification lists indicated by the departements of Pharmacovigilance.
- Capture and management of the complaints along to the specification lists indicated by the departements of Quality Assurance.
- Management of the flow and elaboration of the personal data with access to Webmail with a safety certificate SSL through a dedicated intranet.
- Production and transmission of the reports according to the costumer regarding the activities of the nursing staff stocked for patient/region/service, management of the complaints, the adverse events, the forms of application to the service and of the materials.
- Capture of the consense for the access to the personal data of the patients.
- Market Access: statistic analysis with monitored adherence to the therapy and realisation of studies HTA through a dedicate organisation.
- Management of the rotation of the sites of injection.
- Psychological and psychotherapeutic support for the patients and their families when they need chronical therapies with the objective of favoring the compliance to the cure and the acceptance of the pathology.
- Medical and nursing assistance at the agencies, private hospitals, rest homes, communities, residences and private houses. Collaboration with interprofessional funds.
- OUR CO-WORKERS
- Our professionals are exclusively dedicated to the costumer and they are qualified with: Master's_degrees; Certificate anti-pedophilia (D.Lgs 39/2014); Advanced skills in organisation and personal relations; Reliability, privacy and precision; High dialectic skills and a defined presence.
- THE GOVERNANCE
- The governance that we adopt aims to locate new room for improvement in full compliance with the company values that we have identified.
- Our system is based on code, methods and procedures which regulate the activity of the various organisational functions and which are regularly checked and revised to meet the development of the regulations and the change of the procedures.
- We have started a procedure for the certification of the management system for the UNI EN ISO 9001:2008 quality system in order to offer a service that is more and more focused on the need of our current and future customers; in cooperation with our IT team we are also creating a web page called "AFIONLINE" which can be used by both the patients and the healthcare assistants to ask for consumer products, to schedule a nursing examination and to lodge complaints. This new web page will integrate the existing communication channels, namely toll free number and fax.
- Obviously the web page "AFIONLINE" can be personalized by the customer thanks to the drop-down menu, the logo and so forth.

MARKETING UNIT

In order to meet the increasing and different demands of our customers, we have created a marketing unit with the aim of offering advice and temporary management in the marketing field

of the services dedicated to health and wellness, following an extensively tested methodology:

- Analysis of the customer's needs
- Study of the feasibility of the solutions
- Management of the start to finish and of the project phases through the project management techniques
- Coordination of the allocated human and financial resources
- Risk assessment and collective plans development
- Implementation of the specific procedures
- Creation of the papers relating to the work in progress
- Check of the achievement of the aims according to the cost-time-quality constraints

Study and realisation of the Patient Support Programs to support chronic patients regarding the compliance and the treatment adherence:

- patient centricity as an incentive to promote access to the products, through a more suitable application, in order to improve the treatment adherence and the health outcomes
- types of projects focused on the patient (prevention, education to diseases and education to a proper use of drugs and devices, audit and screening disease management, support for the patients and caregiver, home care and home delivery).

Main advantages of the patient centric projects: adherence, recognition of the patients' needs, appropriateness, innovation, easy treatment management.

ORGANISATIONAL MODEL 231 AND CODE OF ETHICS

We have adopted an organisational model in line with the legislative decree n. 231/01, in order to prevent the commission of offences which can threaten the management of the Company if these offences are put in place for the profit and/or advantage of the Company itself.

The code of ethics represents our charter of values because it states the principles on which we base our operations to conduct the activities from an ethic point of view, that is to say in a transparent, correct and fair way.

SERVICES

AFI Health Care Solutions services are addressed to Companies that work in the health field. These services are provided on the whole national territory thanks to the support of skilled partners.

HOME BLOOD SAMPLE COLLECTIONS AND MEDICAL DIAGNOSTICS

We have drawn up an agreement with a leading Company in Europe in the field of medical diagnostics.

Thanks to this cooperation we are able to give the patients, together with your drugs and devices, a service of home blood chemistry sample collection with the help of our nurses who work throughout the national territory.

We are able to offer more than 1.000 different types of tests in most parts of Italy, both private examinations and those part of the state run health care; the advantage is to achieve uniformity in the results because analysis kits common to all associated labs are used.

We remain at your disposal if you require any further information about this new service.

PERSONNEL TRAINING

Operating in the respect of the procedures of AFI Health Care Solutions (that can be consulted if needed), all the personnel and professionals involved in the project receive a specific training and updating on the use of the device, on how to manage complaints and on the procedures to report the adverse events (ADR). In case of changing the nursing professionals, the duty of AFI HCS, is to provide the new personnel with a complete training before making it operative.

All AFI HCS personnel that receive training is supposed to fill in a form called "training form" that will be registered and archived.

Every nurse that works for AFI HCS is linked to it with a contract and he's supposed to respect the ethic code of behaviour (D.lgs n.231/2001 Italian Law) included in the Organizational Model of Management and Control of AFI HCS.

All the nurses who works with AFI HCS are subscribed to ENPAPI (Ente Nazionale di Previdenza e Assistenza delle Professioni Infermieristiche), have a previous experience in door-to-door assistance, operate as per free-lance practice (with a VAT), are not employed by public organizations and own the certificate anti-pedophilia (D.lgs n.39/2014).

SERVICES MANAGEMENT

The offered service is provided with the consequent methodology in respect of AFI HSC 's procedures.

- Toll-free number available 09.00-13.00 and 14.00-18.00 from Monday to Friday.

FYI: the toll free number can be dedicated (suggested choice to reduce the wait time of the client).

It is available upon request an answering service 24/7, a personalised e-mail, a web site and the fax number of AFI HCS.

AVAILABLE TOLL-FREE NUMBER

Of the Prescriptive Centre and the Doctor for:

- Requesting the first appointment of the nurse to the prescriptive centre, the doctor's ambulatory or the patient's house.
- Requesting the material for the courses in case is the centre itself to do them.
- Requesting emergency supplies (pens and injection devices).
- Requesting possible follow up appointments.
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Of the patient for:

- Requesting the first appointment.
- Requesting the follow up appointment.
- Requesting consumer products (pens and injection devices).
- Requesting emergency supplies.
- Requesting instructions to change the dose (with the authorisation of the doctor of the Prescriptive Centre).

ANSWERING SERVICE (24/7 OPEN), PERSONALIZED E-MAIL, WEB SITE, FAX NUMBER OF AFI HCS ARE AVAILABLE FOR:

Of the Prescriptive Centre and the Doctor for:

- Requesting the first appointment of the nurse to the prescriptive centre, the doctor's ambulatory or the patient's house.

- Requesting emergency supplies.
- Requesting the material for the courses in case is the centre itself to do them.

Of the patient for:

- Requesting the first appointment.
- Requesting the follow up appointment.
- Requesting consumer products (pens and injection devices).
- Requesting emergency supplies.
- Requesting instructions to change the dose (with the authorisation of the doctor of the Prescriptive Centre).

Of the nurse for:

- Requesting the material for the courses.
- Sending the informed consent filled in by the patient.
- ending the AIFA form to report the adverse events ADR (within 24 hours).
- The personalised e-mail, web-site, fax number of AFI HCS are available for:
- Requesting to the certified storage to send the consumer material for the patients.
- Requesting to the certified storage to send the material for the courses to the nurse or the Prescriptive Centre in case it does them.
- Collecting any communication with the nurse
- Sending within 24h from receiving the report of the adverse events to the Pharmaceutical Surveillance Responsible of client.
- Sending the complaints to the Quality Assurance of client.

OPERATIONS TO SUPPLY THE COURSE

- The patient / Prescriptive Centre / Doctor call the toll-free number to start the service.
- The telephone operator (TO) of AFI HCS takes notes of the call filling in a form with the patient's information.
- The TO then will report the form in a dedicated database.
- the nurse goes to the prescriptive centre, ambulatory or house of the patient to administer the training.
- The nurse, before doing the course, makes sure that the patient reads, fills in and signs the informed consent. Then he keeps a copy of it that will be sent to AFI HCS (according to the art.13 D.lgs 196/2003)
- The nurse, after the course, will fill in a form with the data of the patient (service date, address, age, sex, posology, prescriptive centre, ASL, possible date and reason of the follow up visit).
- At the end of the month, the nurse will send via email/fax to AFI HCS secretariat the administrative documents, visit reports and informed consents that will be added to the patient's record and registered in the database.
- The secretary of AFI HCS will monthly send to client the report divided per date, patient ID, age, sex, posology, region, province, prescriptive centre.

OPERATIONS FOR THE FOLLOW UP VISITS AND COMPLAINTS MANAGEMENT

- Given the data received by client, the number of follow up visits shouldn't be more than 10% of the total of the new patients per year, quoted in 350 unities.
- The follow up visit follows 3 steps: the patient calls the toll-free number or send an email/fax to request assistance.
- Telephone management of the problem reported by the patient.
- If it is not possible to solve the problem via phone call, AFI HCS secretary will ask client the authorization for the nurse's intervention.
- The nurse does the visit, solves the problem and reports to AFI HCS secretary the kind of intervention realized.

If the nurse identify the problem in the malfunction or accidental break of the device, it will be immediately changed with a new one and send the broken one to AFI HCS along with a complaints report. AFI HCS secretary reports on the patient's record the date and description on the intervention done by the nurse, and in case of deficiency/break of the device, creates a complaint that will send, along with the device, to client Quality Assurance departement.

OPERATIONS TO REQUEST AND SEND THE MATERIAL

Via the toll-free number, the personalised email, web-site and fax, all the entities involved (patients, prescriptive centres and nurses) can request to AFI HCS the support and consumer material.

The duty of the telephone operator and AFI HCS secretary is to collect the request, report all the data on the patient's record, add it in the database and send it to the certified storage that will realize the order.

AFI HCS secretary fills in an expiration dates log book every six months so that if a patient doesn't order needles or other consumer material, he will be contacted to have information on the state of his therapy.

N.B.: This data is very important to identify possible drop-out.

AFI HCS secretary manages the devices expired and sends to the patient new material via the certified storage that, if required by Ipsen, will also get the old device back.

AFI HCS secretary manages the stored consumer material for the courses owned by the nurses and controls the supply of material taking in account the minimum amount that they can hold.

AFI HCS will store at its offices a minimum amount of material in order to fulfill any emergency. This material will be sent upon request of the patients or nurses via a courier. The shipping costs will be charged to client.