Polmedics Ltd

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Inspection Report

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Overall summary

We carried out an announced inspection on 10 February 2017 of Polmedics Ltd (the provider) at their administrative head office located at 36 Regent Place, Rugby CV21 2PN. (We were informed by the provider that all governance and management systems in place were located at this address in Rugby and not the provider address registered with the Commission which is located in Wellingborough. We obtained verbal and written consent from the provider to carry out this inspection at their administrative head office in Rugby).

At the same time, we also carried out unannounced focused inspections of Polmedics Limited – Bristol and Polmedics Limited - Wellingborough on 10 February 2017.

These inspections were carried out due to concerns raised following a series of inspections carried out at Polmedics Limited - Allison Street, Birmingham on 9 & 30 November 2016, Polmedics Limited - West Bromwich on 16 December 2016 and Polmedics Limited - Rugby on 17 December 2016 identifying serious concerns linked to the provider's lack of governance and infrastructure arrangements.

We inspected the provider to assess their governance and leadership arrangements in respect of these concerns, therefore it was not necessary to use all key lines of enquiry.

Our findings were:

Are services safe?

We found that the provider was not providing safe care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

Are services effective?

We found that the provider was not providing effective care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

Are services well-led?

We found that the provider was not providing well-led care in accordance with the relevant regulations. We have told the provider to take action (see full details of this action in the Enforcement section at the end of this report).

Background

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the provider was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Polmedics Ltd was established in 2013 and is an independent provider of dental and medical services including gynaecology, sexual health screening and other services such as consultation services which includes the

Summary of findings

diagnosis and treatment of disease and prescribing of medicines. Consultation services are provided by doctors who are referred to as internists and treats both adults and children. (At the time of our inspection, the provider confirmed that all medical services had been suspended voluntarily based on concerns found during the Commission's inspections of three other locations during November and December 2016. It was the intention of the provider to recommence the provision of medical services in the near future).

Services are provided across seven locations in Birmingham, Bristol, Ealing, Redditch, Rugby, West Bromwich and Wellingborough primarily but not restricted to Polish patients who reside in the United Kingdom (UK). Services are available to people on a pre-bookable appointment basis and we were informed during our inspection that patients book appointments by contacting a call centre located in Poland. The provider advertise a variety of other additional services on their website such as cardiology, dermatology, midwifery, psychiatry, paediatric and orthopaedic services however, we were advised prior to our inspection that these additional services are no longer provided. The range of services advertised on the providers website differs at each location. We were informed by the provider that there are approximately 33,000 registered patients across all Polmedics Ltd locations.

Polmedics Ltd (the provider) is registered with the Care Quality Commission to provide the regulated activities of diagnostic and screening procedures, family planning, maternity and midwifery services, surgical procedures and treatment of disease, disorder or injury.

The provider had not ensured that a registered manager was in place at each location. (A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run). At the time of our inspection, one of seven locations had a registered manager in place, registered manager applications were in progress for five locations.

We were told that the provider had made recent changes to staffing levels and confirmed that 50 members of staff were employed across all locations. The staffing structure included three directors (one director acted as company secretary and one director who is a dentist acted as medical director). We were told that recent changes had taken place within the board of directors, there were previously four directors in post however, we were verbally informed that one director was dismissed by the provider due to a referral being carried out to the General Dental Council (GDC) we were unable to see any documented evidence of the dismissal process followed during our inspection. Each director has a specific area of responsibility such as premises and maintenance management, appointments system and scheduling, IT and recruitment. The provider employed one nominated individual who carried out the role of operational manager to oversee the management of all seven locations. There is a finance and human resources department which we were informed is located on the ground floor of Polmedics - Allison Street, Birmingham consisting of four members of staff. We were informed of seven managers being in post, one at each location (some managers were still awaiting commencement of their post dependent upon either a DBS check being received or confirmation as a CQC registered manager being received). The provider also employed a number of dentists, trainee dental nurses and receptionists across all locations. Some clinicians including dentists working in the locations live in Poland and travel to England on a regular basis to carry out shifts at each location.

Our key findings were:

- There was an ineffective, governance framework in place to support the delivery of the strategy and good quality care. There was a lack of effective systems and processes in place for identifying, assessing and monitoring risks and the quality of the service provision across all locations.
- There was an ineffective leadership structure in place, there was a lack of suitably trained and experienced management support in place on a daily basis at each location and there was a lack of clinical leadership and oversight at both location and provider level.
- There was no process for ensuring that the board of directors were fit and proper persons to manage the service. This is a duty required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Key documentation on the recruitment of individuals was missing from personnel files.

Summary of findings

- The provider had not ensured that a registered manager was in place at each location. It is a requirement of registration with the Care Quality Commission where regulated activities are provided to have a registered manager in place.
- There was a lack of identification of risks and ineffective risk management processes in place at location and provider level to mitigate these through effective risk registers or appropriate discussion and acknowledgement of risk where highlighted by internal staff.
- The professional registration of clinical staff working at all locations were not all routinely checked at employment. The provider did not ensure that a system was in place within the organisation to ensure professional registration was routinely checked on an ongoing basis.
- The provider did not have an effective system or process within the organisation to ensure appropriate checks of current medical indemnity insurance had been carried out on all clinicians upon commencement of employment.
- There was not effective governance or monitoring processes in place to ensure that children and young people were safeguarded from abuse and improper treatment. The provider had not ensured a safeguarding lead was in place for each location. There was no policy in place in relation to female genital mutilation (FGM) and child sexual exploitation.
- There was poor quality monitoring of services in areas such as consent with clinicians having limited knowledge and understanding and not adhering to national guidance.
- The provider did not hold formal, structured, minuted meetings at either provider or location level. Meetings were either held informally or were ad-hoc. Staff we spoke with told us meetings at location level were not recorded.
- There was not an effective system in place for the reporting and investigation of incidents or lessons learned as a result. The provider did not have a process in place to ensure oversight of the reporting, recording and investigation of any incidents or significant events which may have either occurred or been reported across all locations.
- The provider had not ensured adequate arrangements were in place across all locations to respond to emergencies and major incidents as the provider had not acted upon all previous concerns raised in a timely manner during location inspections carried out during November and December 2016.

We identified regulations that were not being met and the provider must**:**

- Ensure an effective governance and leadership framework is in place to monitor the services provided and reduce the risk of harm.
- Ensure effective systems and processes are in place for identifying, assessing and monitoring risks and the quality of the service provision across all locations such as implementing a system of clinical audits and a system of clinical supervision/mentorship and clinical oversight for all clinical staff including trainee dental nurses. Ensure all clinical staff are competent to ensure the safety of patients using the service.
- Ensure appropriate systems are in place to properly assess and mitigate against risks including risks associated with infection prevention and control, legionella, managing emergency situations and premises and equipment.
- Ensure a review is undertaken of chaperone arrangements and that chaperone training is undertaken by staff who perform chaperone duties.
- Ensure arrangements to safeguard children and vulnerable adults from abuse reflect relevant legislation and local requirements.
- Ensure effective processes for timely reporting, recording, acting on and monitoring of significant events, incidents and near misses are in place across all locations.
- Ensure an effective process is in place to monitor patient care records so that patient information is recorded in line with the 'Records Management Code of Practice for Health and Social Care 2016.
- Ensure the practice's recruitment policy and procedures are suitable and the recruitment arrangements are in line with Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, with necessary employment checks are in place for all staff and the required specified information in respect of persons employed by the provider is held.

Summary of findings

- Ensure a registered manager is in place at each location. (It is a requirement of registration with the Care Quality Commission where regulated activities are provided to have a registered manager in place).
- Review processes in place in relation to clinicians medical indemnity insurance to show that appropriate checks of clinicians own insurance is carried out prior to commencement of employment.
- Ensure that staff taking consent have the appropriate knowledge, skills and competence. Ensure consent is sought from adults and children including those that are vulnerable in line with legislation and guidance.

There were areas where the provider could make improvements and should:

- Ensure a system of appraisals is in place so all members of staff across the organisation receive an appraisal at least annually.
- Ensure appropriate policies and procedures are implemented, relevant to the organisation so all staff are aware of and understand them.

Enforcement action was taken against the provider on the 15 February 2017, when we issued an urgent notice of decision to immediately suspend their registration as a service provider (in respect of all regulated activities for which they are registered) for a period of six months. We took this action because we believed that a person would or might be exposed to the risk of harm if we did not take this action.

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found that the provider was not providing safe care in accordance with the relevant regulations.

- Arrangements to safeguard children and vulnerable adults from abuse did not reflect relevant legislation and local requirements. The provider did not ensure that clearly defined and embedded systems, processes and practices were in place to keep patients safe and safeguarded from abuse across all locations.
- During our inspection, we were informed by the provider that there was no lead in place for safeguarding adults and children for each location.
- There was no evidence of a safety improvement culture and the board of directors were unable to provide evidence to assure CQC that systems and processes were in place across their areas of responsibility as directors.
- There was not an effective system in place for the reporting and investigation of incidents or lessons learned as a result.
- The provider did not have an effective system or process in place to ensure that adequate medical indemnity insurance was in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment.
- The provider did not hold a record of Hepatitis B status and other immunisations for clinical staff across all locations who had direct contact with patients' blood for example through use of sharps. There was no process in place to ensure all clinical members of staff Hepatitis B status and other immunisations were checked or immunisation arrangements for staff were in place.
- The provider had not ensured there was an effective system in place for identifying, capturing and managing issues and risks across the organisation. Risks to patients were not assessed and well managed. There was no risk register in place at location or provider level.
- The provider did not have a system or process in place to ensure there was a consistent approach at all locations to ensure equipment was appropriately maintained and monitored.
- Due to the inconsistency of evidence provided prior to, during and following our inspection and previous location inspections it was impossible to be assured who was employed and scheduled to work at all locations**.** We were not assured that adequate staffing levels were in place to meet the demands of the service.
- The provider did not ensure safe systems and processes were in place for the safe and effective use of medicines.

Are services effective?

We found that the provider was not providing effective care in accordance with the relevant regulations.

- The provider did not have an effective process in place to enable monitoring of outcomes for patients or quality improvement. Clinical audits did not take place however, we were informed that plans were in place to address this.
- There was no formal process in place to ensure all members of staff across all locations including the board of directors received an appraisal.
- There were no systems in place to monitor patient care records to ensure that patient information was recorded in line with the 'Records Management Code of Practice for Health and Social Care 2016. There was no system in place to ensure that an accurate, complete and contemporaneous record was maintained for every patient.

Summary of findings

- The provider did not have an effective, overarching system or process in place to ensure that all newly appointed staff had completed a comprehensive induction and training programme at the location in which they were intended to work. Not all locations had a suitably qualified manager in place on a daily basis to oversee newly appointed staff.
- We were not assured that all staff sought patients' consent to care and treatment in line with legislation and guidance.
- We were not assured that staff were supported by the provider in their continued professional development (CPD).
- There was no evidence of formal clinical supervision, mentorship and support in place for all members of staff including trainee dental nurses.

Are services well-led?

We found that the provider was not providing well-led care in accordance with the relevant regulations.

- The provider had not ensured that a registered manager was in place at all locations.
- The provider did not have an effective, overarching governance framework in place across the organisation to support the delivery of the strategy and good quality care. There was a lack of effective systems and processes in place at provider and location level for assessing and monitoring risks and the quality of the service provision.
- There was an ineffective leadership structure in place, with a lack of suitably trained and experienced management support on a daily basis at each location. There was a lack of clinical leadership and oversight at both location and provider level. There was no system of appraisals in place for members of staff or directors.
- There was no adherence to the fit and proper person's regulation despite this being introduced in 2015. At the time of our inspection, the provider was unable to provide evidence of a DBS check for all directors. These were not all held on personnel records for all directors at the head office. Evidence of missing DBS checks were provided following our inspection.
- We were not assured of the leadership, openness and transparency of the directors as no learning had been shared following concerns raised during previous inspections of other locations.
- Appropriate systems and processes were not in place for the provider to be assured that all dental and medical staff were registered with their regulatory body or that doctors had undergone revalidation.
- The provider did not hold formal, structured, minuted meetings at either provider or location level. Meetings were either held informally or were ad-hoc. Staff we spoke with told us meetings at location level were not recorded.

Polmedics Ltd

Detailed findings

Background to this inspection

The inspection was carried out on 10 February 2017. Our inspection team was led by a CQC Lead Inspector and was supported by an Assistant Inspector, Inspection Manager, Deputy Chief Inspector of Primary Medical Services, GP Specialist Advisor, Leadership and Governance Specialist Advisor and an Enforcement Inspector. The team was also supported by a Polish translator.

Prior to this inspection, an announced inspection had been carried out at Polmedics Limited – Allison Street in Birmingham on 9 and 30 November 2016. On the 11 November 2016, the Commission served an urgent notice of decision to impose conditions upon the registration of this service provider in respect of a regulated activity. This notice of decision included the following condition:

- The registered person must not provide any services under the regulated activity of diagnostic and screening procedures, surgical procedures, maternity and midwifery and treatment of disease, disorder or injury until 11 January 2017.

Following the Commission's decision to impose conditions upon Polmedics Limited – Allison Street, due to the serious concerns identified an unannounced focussed inspection was carried out at West Bromwich on 16 December 2016. Serious concerns were also found at Polmedics Limited – West Bromwich and on 16 December 2016, the Commission served an urgent notice of decision to impose conditions upon the registration of this service provider in respect of a regulated activity. This notice of decision included the following condition:

- The registered person must not provide any services under the regulated activity of diagnostic and screening procedures, surgical procedures, maternity and midwifery and treatment of disease, disorder or injury until 31 January 2017.

An unannounced focussed inspection was carried out at Polmedics Limited – Rugby on 17 December 2016 and serious concerns were found.

On the 19 December 2016, the provider took actions to temporarily close all Polmedics Ltd locations which included Polmedics Limited until 31 January 2017. This action negated the requirement for CQC to take urgent enforcement action as patient groups in relation to whom we had major safety concerns had their safety risks addressed by Polmedics Ltd suspending their services.

Following the actions taken by the provider to temporarily close all locations, we were informed by the provider of their intent to re-open locations with the exception of Polmedics Limited – Redditch and Polmedics Limited – Allison Street prior to the 31 January 2017 due to the provider confirming these locations were compliant with the Commissions fundamental standards.

During our visit on 10 February 2017 we:

- Used information gathered following inspections of three locations carried out during November and December 2016 to inform our inspection.
- We inspected the provider's administrative head office in Rugby on 10 February 2017.
- We interviewed the board of directors, the nominated individual and two managers who were employed at the Ealing and Rugby locations.

Detailed findings

- Additional inspection teams carried out unannounced focused inspections of Polmedics Limited – Bristol and Polmedics Limited – Wellingborough on 10 February 2017. (Separate inspection reports have been published for these inspections).
- We conducted a tour of the premises.
- We reviewed a range of information which included policies and procedures, patient care records and staff recruitment and training records. We also looked at the electronic appointments system.
- We did not speak to patients during our inspection.
- Following our inspections we spoke with other stakeholders such as NHS England and the General Medical Council about our concerns.

Are services safe?

Our findings

Reporting, learning and improvement from incidents

The provider did not have a process in place to ensure oversight of the reporting, recording and investigation of any incidents or significant events which may have either occurred or been reported throughout all locations.

- During our inspection, we were informed of two incidents which had occurred of which the provider was aware of, one related to a theft and one related to a needle stick injury. There was limited documented evidence of these incidents, actions taken as a result or lessons learned and shared with staff. We saw evidence of an email dated 7 February 2017 from a manager informing the nominated individual and one director of a needle stick injury that had occurred. A dental nurse had suffered an injury to her hand with an orthodontic fork. (The board of directors were advised during discussion that this injury was not a needle stick injury). The report stated that the dental nurse had attended an accident and emergency department and that the manager would submit a report to the Health and Safety Executive (HSE). We did not see any evidence of this report being completed or sent to HSE, or any details of any investigations, actions taken as a result or discussion in meeting minutes. Following an interview with this manager, we were informed that a meeting had been arranged with the directors to discuss this in more detail on 20 February 2017.
- During our location inspections, we observed that there was not an effective system in place to enable staff to report incidents, near misses or significant events. We did observe that a policy was in place however, we spoke with staff members who were unable to explain whether incident report forms were available for staff or the location of these forms and a policy. We had seen evidence of incidents which had occurred and had been identified by members of staff at some locations which had not been reported, recorded or evidence of discussion and lessons learned as a result for example, incidents in relation to storage of clinical waste and sharps. We found that a number of complaints merited further investigation as a significant event in order to promote shared learning and prevent reoccurrence. The practice had not investigated these issues as significant events. We also found evidence of incidents and concerns identified during an internal inspection carried out by the provider in October 2016 which would have constituted further investigation and a significant event analysis. Formal meetings did not take place at these locations, there was no evidence of formal discussion in relation to any incidents which may have been required to be reported.

Duty of Candour

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 places a statutory duty of candour requirement on all providers of health and social care. This regulation requires the provider to notify the relevant person that a notifiable safety incident has occurred, to provide reasonable support to the relevant person in relation to the incident and to offer an apology.

- There was no policy in place for the duty of candour requirements which meant staff did not have a process to follow when they were dealing with incidents.
- There had been no training for staff on the requirements of the regulation.
- We interviewed members of the board of directors and the nominated individual and we were not assured that the directors we interviewed were fully aware of the requirements the regulation placed upon the provider.

Reliable safety systems and processes (including safeguarding)

The provider did not ensure that clearly defined and embedded systems, processes and practices were in place to keep patients safe and safeguarded from abuse across all locations, for example:

- During our inspection, we were informed by the provider that they did not have a lead in place for safeguarding adults or children for each location. One manager we spoke with told us that the nominated individual was the safeguarding lead. The nominated individual had told us that managers at location level were safeguarding leads. A copy of the safeguarding adults and children policy was not held at the head office. The provider confirmed that there had been no safeguarding referrals made from any locations. Although services were provided to both adults and children, the provider did not have robust safeguarding

processes in place, therefore we could not assure ourselves on the day of inspection that processes in place at the time of our inspection kept both adults and children safe and safeguarded from abuse.

- During our location inspections, we saw that a policy and protocol was in place for staff to refer to in relation to adults and children who may be the victim of abuse or neglect however, this policy did not refer to a named safeguarding lead. Information was available in the practice that contained telephone numbers of whom to contact outside of the practice if there was a need, such as the local authority responsible for investigations. However, staff we spoke with during all inspections carried out were unable to confirm who the safeguarding lead was and staff we spoke with were unsure of the process for reporting a safeguarding incident.
- The provider did not have an effective system or process in place to ensure all members of staff throughout each location had completed safeguarding children and adults training. We were informed during our inspection that all members of staff had completed the required level of safeguarding training however, we were not assured that we were aware of all staff employed within the organisation. The provider did not have an overarching system in place for collating the records of training, learning and development needs of staff. Formal meetings were not held at either provider or location level to discuss and document safeguarding concerns which may have arisen.
- We were informed by the provider that there was no policy in place for female genital mutilation (FGM) or child sexual exploitation.
- The provider had not ensured that trained chaperones were available during all internist and gynaecology clinics, across all seven locations during opening hours. At the time of our inspection, the provider had suspended medical services although it was their intention to re-commence these services as soon as possible. We were informed by the provider that a minimum of two trained chaperones were available at each location. However, the locations advertised that services were available seven days per week between the hours of 9am and 9pm. The provider was unable to provide evidence that a chaperone was available throughout all opening times across all locations or evidence of chaperone training for two chaperones per location. During an interview with the board of directors, we were told that every patient was seen in the presence of a dental nurse trained in chaperoning however, they were unable to confirm how many chaperones were in place or trained across the organisation. The nominated individual confirmed there were no chaperone training records available during our inspection.
- The provider did not hold an overarching record of Hepatitis B status or other immunisations for all clinical staff members across the organisation who had direct contact with patients' blood for example through use of sharps. During our location inspections, we saw there was no process in place at location level to ensure Hepatitis B status or other immunisation records were obtained for all clinical staff. However, during our inspection carried out at the head office address, we saw evidence of scanned immunisation records for some members of staff on google drive. As we could not be assured that we were aware of all clinical staff employed by the provider we could not be assured that the provider had an effective system in place to ensure all immunisation records were obtained.

Medical emergencies

The provider did not have adequate arrangements in place across all locations to respond to emergencies and major incidents as the provided had not acted upon previous concerns raised during location inspections carried out during November and December 2016.

For example:

- During our location inspections, we observed that there were some gaps with respect to the recommended emergency medicines and equipment. For example, during our inspection of Polmedics Limited – Allison Street, Birmingham on 9 November 2016, we observed that there were some gaps with respect to the recommended emergency medicines and equipment. For example, the practice had in place emergency medicines as set out in the British National Formulary guidance for dealing with common medical emergencies in a dental practice except in one instance. The practice had in place ampoules of Diazepam instead of the recommended Buccal Midazolam format. We also noted that a volumetric spacer used in

conjunction with the salbutamol inhaler was not available. Following these concerns being addressed with the provider, a further visit was carried out at this location on 30 November 2016, these concerns had still not been addressed. Further location inspections took place at Polmedics Limited – West Bromwich on 16 December 2016 and Polmedics Limited – Rugby on 17 December 2016 and similar concerns were found. The provider had not acted upon these concerns already raised at previous locations to ensure adequate arrangements were in place across all locations to respond to emergencies or major incidents.

- Other concerns found during our location inspections included emergency resuscitation equipment that was not in line with the Resuscitation Council UK guidelines. At one location we inspected, there was no self-inflating bag, no portable suction device and only one size of oropharyngeal airway was available. The practice did have access to oxygen for use in an emergency. However, we noted the oxygen cylinder was broken. It was not capable of administering oxygen. The oxygen mask was attached and was left draped on the floor of the decontamination room and was visibly dirty. We were told this had broken the day before and a new one would be sourced. We saw evidence that another oxygen cylinder was sourced during our inspection.

Staffing

Due to the inconsistency of evidence provided prior to, during and following our inspection and previous location inspections it was impossible to be assured who was employed and scheduled to work at all locations**.** We were not assured that adequate staffing levels were in place to meet the demands of the service. For example:

- Prior to our location inspections carried out during November and December 2016, we were informed by the provider that services were provided to approximately 2,000 patients at one location. However, we were later informed that services were provided to approximately 33,000 patients across all seven locations. During our inspection at the head office address, we were provided with an up to date staffing structure which confirmed details of the board of directors and management structure, however this document did not give actual numbers of staff employed across all locations. We were told verbally that they had increased staffing levels to 50 across all locations however, we requested a copy of staff details from their payroll system to determine the number of staff employed and this detailed 22 members of staff employed. Following a tele-conference meeting that had taken place between the Commission and the provider on 26 January 2017, we were provided with details of staffing across five locations which included the board of directors and management team which detailed 41 members of staff and included two directors.
- We were not provided with accurate information of all staff employed to work at each of the seven locations. Most staff resided in Poland and travelled to England on a regular basis to carry out shifts at the practice and then returned to Poland following completion of their shift. We were informed that staff were recruited mainly through word of mouth and through friends and may also have had other employment in Poland.
- The provider did not have an effective process in place at either their head office address or throughout the locations we inspected to ensure regular checks of GMC, GDC and other professional registrations were carried out.
- We were provided with evidence in January 2017 that all dentists and qualified dental nurses that we were aware of had current registration with the General Dental Council (GDC), the dental professionals' regulatory body. Doctors had current registration with the General Medical Council (GMC) the medical professionals' regulatory body. However, these doctors did not have a current responsible officer. (All doctors working in the UK are required to have a responsible officer in place and required to follow a process of appraisal and revalidation to ensure their fitness to practice).
- The provider did not have a system or process in place to ensure effective clinical supervision including appropriate support, training and professional development of all dental and medical staff including trainee dental nurses. We were informed that a director had recently been appointed as medical director. However, this director lived and undertook his main employment in Poland and worked in the UK for approximately one day per week for Polmedics Ltd. This director informed us that staff could contact him if required by using Skype or WhatsApp.

Are services safe?

- During our location inspections, we were informed that the provider did not always ensure references were obtained from previous employers prior to offers of employment being made to newly recruited members of staff.
- The provider did not have an effective system or process in place to ensure that clinicians had adequate medical indemnity insurance in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment.

Monitoring health & safety and responding to risks

The provider had not ensured there was an effective system in place for identifying, capturing and managing issues and risks across the organisation. Risks to patients were not assessed and well managed. There was no risk register in place at location or provider level.

We were informed during our inspection that a system was in place to monitor infection control rates and patient outcomes. We were also informed that sterilisation audits were carried out and monitored by mangers at location level however, there was a lack of experienced management support in place at each location on a daily basis. Those managers that were in post were relatively new to their role and inexperienced with the exception of a manager employed at the Ealing location.

There was no evidence of a safety improvement culture and the board of directors were unable to provide evidence to assure CQC that systems and processes were in place across their areas of responsibility as directors. We asked the directors during an interview how they ensured that all premises where regulated activities were provided from were fit for purpose. We were told that one director was responsible for carrying out regular visits of each premises however, they were unable to provide evidence of visit reports.

During our location inspections, we found evidence that risks to patients were not assessed and well managed. For example:

- Not all members of staff had received up to date health and safety training. We did not see evidence that regular fire drills had taken place.
- At one location we inspected, there were some risk assessments in place to monitor health and safety of the premises, staff and service users. For example, we saw a risk assessment which had been carried out of the decontamination room however, this had last been carried out in August 2013 and required review. A legionella risk assessment had been carried out in March 2016. This assessment advised that monthly water temperatures should be recorded at the sentinel outlets (a sentinel outlet is the nearest and furthest hot and cold water outlet from the water storage tank or cylinder). This had not been done.
- At another location we inspected, the last fire risk assessment had been carried out in October 2016 by an external specialist. We noted that there was an action item in this risk assessment that a five yearly fixed wire testing of the electrical hard wiring system in the premises was required. The provider had recorded an action item to contact the landlord of the property as the landlord was responsible. We were unable to see evidence that this had been carried out. The provider informed us that the certificate was in a health and safety folder, we were unable to find this. We requested a copy of this to be provided to the Commission immediately following our inspection however, this was not provided.

Infection control

We were informed during our inspection that one director was responsible overall for ensuring there was a consistent approach to infection control across all locations. This director told us that he gained assurance of compliance by carrying out reviews of infection control audits and liaising with location managers but we saw no evidence to corroborate this with audits at either a provider or location level. During our location inspections we found varying levels of concern. For example:

- The provider had ensured there was an infection control policy in place however, not all staff we spoke with were aware of who the infection control lead was. The policy was not reflective of processes in place at the times of our location inspections.
- The provider did not hold an overarching training record for all staff employed across all locations and were unable to give assurance that all staff had received infection prevention and control training. Following an

inspection of one location, we asked the provider to submit evidence of this training for all staff immediately following our inspection however, this was not provided when requested.

- We observed during some locations inspected that spillage kits were not provided to deal with the spillage of bodily fluids such as urine, blood and vomit. We did note that one location did not have a mercury spillage kit available.
- The provider had not ensured safe processes across all locations in relation to sterilisation of dental equipment. For example, at one location we inspected we observed that single use suction tubes which should be disposed after first use were sterilised and used again. During the inspection we noted several plastic saliva ejectors in the dirty box. We asked a dental nurse if these were to be sterilised. They confirmed they were due to be sterilised. (These instruments are single patient use only and should not be sterilised and re-used).
- At one location we inspected, we spoke with staff and reviewed records relating to the validation and testing of the equipment used in the decontamination and sterilisation of used instruments. There were many gaps in the validation and testing processes. Staff were unclear about the daily automatic control test for the autoclave. There was a checklist which indicated this test was carried out even though staff were unaware of how to conduct the test. The weekly protein residue test on the ultrasonic bath had last been completed in June 2016. The ultrasonic activity test had last been completed in May 2016. (This test should be carried out on a quarterly basis).

Premises and equipment

The provider did not have a system or process in place to ensure there was a consistent approach at all locations to ensure equipment was appropriately maintained and monitored. During one location we inspected, we observed areas of concern. For example:

- X-ray equipment was located in one of the dental surgeries. We saw a critical examination and acceptance test had been carried out on 8 October 2013. Within this there were two actions which had been highlighted to ensure the x-ray equipment was safe to use. One of these actions related to the position of the operator whilst taking an x-ray. This stated "the operator stands inside the decontamination room and views the patients and warning lights through a viewing panel provided in the wall. If the viewing panel is made of conventional glass, it should be replaced with lead glass in order to provide adequate protection to the operator. The practice should consult its RPA regarding this matter". During the inspection we observed an x-ray being taken. The dentist did not follow the guidance from the report and did not observe the patient whilst the x-ray was being taken. We also did not see any evidence the radiation protection advisor (RPA) had been consulted and lead glass had been put in the viewing panel. The report also stated the practice should review the use of self-developing x-rays in order to reduce the dose to patients. The practice was still using self-developing x-rays.
- We found out of date swab collection and transport kits for use in sexual health screening which had expired in November 2016. These kits should not be used after the date of expiry as the results may be unreliable.

Safe and effective use of medicines

During our inspection, we looked at the management systems in place for managing medicines across all locations at provider level. The provider did not ensure safe systems and processes were in place to ensure the safe and effective use of medicines. For example:

- During our inspection, we were informed that all clinicians' working within each location had signed up to the relevant websites to enable receipt of national patient safety alerts such as those issued by the Medicines and Healthcare Regulatory Authority (MHRA). There was no evidence at the head office of any system or process in place for the provider to be assured that alerts were being received, disseminated and actioned where necessary. During our inspection, we spoke with a manager of a location who told us that they had registered with the MHRA website to receive alerts approximately one year ago. This manager was able to tell us about one alert received in relation to an emergency medicine and told us this was acted upon however, this was not recorded and so there was no evidence to gain assurance that this had been actioned. We were told that alerts were discussed in meetings at location level but that these meetings were not recorded. During our location level inspections, there was no evidence of alerts received that were pertinent

to dentistry or general medicine that had been issued by MHRA so that they could be discussed by members of the medical or dental team. We did not see evidence of discussion during meetings held at location level. Staff we spoke with during these inspections were unable to explain the process for the receipt and dissemination of MHRA alerts or any alerts that had been acted upon. During all location inspections carried out, there was no evidence seen to show that staff understood and followed the process for the receipt and dissemination of these alerts.

- We were informed during an interview with one of the directors that a process was in place to monitor prescribing rates for dentists and doctors however, the director was unable to provide evidence of this process.
- All prescriptions were issued on a private basis and we observed that all prescription pads were not always stored securely at some locations. At one location we inspected, blank private prescriptions were left unsecure, on a desk in an unlocked room, these prescriptions had been pre-stamped with the name and GMC number of a doctor.
- The provider did not ensure audits of medicines or prescribing were carried out across all locations. There were no medicines management policies in place at location or provider level.

Are services effective?

(for example, treatment is effective)

Our findings

Monitoring and improving outcomes for patients

The provider did not have an effective process in place to enable monitoring of outcomes for patients or quality improvement at either provider or location level. During our inspection of the head office, we were informed that the nominated individual carried out clinical audits for the organisation however, they were unable to provide evidence of any audits as we were told that they were not located at the head office address but were located at the nominated individual's home address. (a nominated individual is a senior person, with authority to speak on behalf of the organisation about the way that regulated activity is provided). We were told that evidence of these audits would be provided immediately following our inspection however, no evidence was provided. During location level inspections carried out, we were unable to see evidence of effective processes in place to enable monitoring of patient outcomes or quality improvement.

We were informed that the medical director would take responsibility for completing audits of prescribing and record keeping bi-annually across all locations however, as he had commenced this role in December 2016 he had not carried out any audits at the time of our inspection.

During our location inspections, we found concerns in relation to medical records. Patient information was not always recorded in line with the ' Records Management Code of Practice for Health and Social Care 2016. For example:

- Medical records we looked at which were completed primarily by both dentists and doctors were inconsistent. Some records were illegible, we observed that some records did not always contain details of basic observations, patient history, follow up advice given or referral information to secondary care providers. Not all care records were signed or dated appropriately and some records were written in Polish and were illegible when translated.

During our inspection at the head office, we were informed that all clinical staff had recently completed medical record training and that managers across all locations were required to complete a record keeping template and report any concerns found to the medical director. We were also informed that all medical records were now documented in English. As this inspection had taken place at the head office, and all patient care records were in paper format and stored at location level we were unable to evidence to show whether this process had been implemented across all locations since our last inspections carried out.

Staff training and experience

The provider did not have an effective, overarching system or process in place to ensure that all newly appointed staff had completed a comprehensive induction and training programme at the location in which they were intended to work. Not all locations had an appropriately qualified manager in place on a daily basis to oversee newly appointed staff. We were provided with evidence of a completed induction document for a newly recruited member of staff however, this member of staff was not present during our inspection and so we were unable to discuss their induction process with them.

During our location inspections we found concerns in relation to staff inductions, training and experience. For example:

- At one location we inspected, comprehensive records of training were not held and we were unable to locate any training records in the recommended core subject areas by the General Dental Council including, infection control, dental radiography, safeguarding and dealing with medical emergencies. We asked the provider to forward details of staff training however, this was not provided for all members of staff.
- At another location we inspected, we spoke with a clinical member of staff who had recently been employed. They told us that they had a basic induction carried out by a manager however; this induction did not include any infection control training. They were unable to explain the full process for reporting significant events and serious incidents and were not able to explain the location of emergency medicines and equipment.

The provider did not have a process in place to ensure a system of appraisals was implemented across all locations to ensure the learning needs of staff were identified. During our location inspections, we saw that an effective system of appraisals had not been implemented and therefore we were not assured that the provider had oversight of the learning needs or welfare of staff on a daily basis.

Are services effective?

(for example, treatment is effective)

The provider did have an employment and induction policy dated 1 July 2016. However, following our location inspections, current employment and induction processes were not reflective of this policy. For example, this policy stated that all staff would undergo an annual appraisal and also that the practice aimed to comply with all current employment legislation. We were not assured of this during any of our inspections carried out.

Consent to care and treatment

We were not assured that all staff sought patients' consent to care and treatment in line with legislation and guidance. Staff we spoke with were unaware of legislation with regards to parental responsibility (under the Children's Act) and were also unware with regards to legislation regarding obtaining consent if an adult patient was unable to give consent.

We discussed with the directors the payment process for patients. We were informed that the provider allowed patients to set up regular standing order payments for those patients who were receiving regular orthodontic treatment such as dental braces. We were also informed that during the period of voluntary suspension of services by the provider that regular payments had continued during this period and that this was causing frustration with patients who required appointments during this period of suspension.

During our location inspections we found inconsistencies in relation to the explanation of fees and patients consent to these fees. For example:

- At one location we inspected, patients were required to sign a written consent form which detailed the fees required. Before patients received any care or treatment they were asked for their consent and the provider acted in accordance with their wishes.
- We were told that any treatment including fees was fully explained to the patient prior to the procedure and that people then made informed decisions about their care. However, the practice did not offer a pre-consultation process to ensure fees were explained and that patients had a 'cooling off' period before committing to the required fee, attending for an appointment or commencing treatment. We were informed that patients were only allowed to pay in cash for services provided at one location we inspected.
- Standard information about fees were detailed on the practice website however, there was no information regarding fees or a schedule of fees displayed in the patient waiting room. Fees were recorded on the patient consent form which they were required to sign during consultation.
- The provider did not have arrangements in place to ensure all locations offered interpreter or translation services as an additional method to ensure that patients understood the information provided to them prior to treatment. However, most patients and staff were Polish and so the provider did not feel there was a need for interpreter services.

Are services well-led?

Our findings

Governance arrangements

During our inspection, we found there was an ineffective, governance framework in place to support the delivery of the strategy and good quality care. There was a lack of effective systems and processes in place for identifying, assessing and monitoring risks and the quality of the service provision. For example:

- There was an ineffective leadership structure in place, there was a lack of suitably trained and experienced management support in place on a daily basis at each location and there was a lack of clinical leadership and oversight at both location and provider level. The provider did not have a system or process in place to ensure effective clinical supervision of all dental and medical staff. The role of the medical director did not cover the full range of governance and responsibilities required. The medical director was a qualified dentist and would not be able to deliver effective clinical leadership to medical doctors in the future when these services re-commence.
- Appropriate systems and processes were not in place for the organisation to be assured at provider level that all dental and medical staff were registered with their regulatory body or that doctors had undergone revalidation.
- The provider did not have an effective system or process in place to ensure that adequate medical indemnity insurance was in place or that appropriate checks of current insurance had been carried out on all clinicians upon commencement of employment.
- There was a lack of identification of risks and ineffective risk management processes in place at location and provider level to mitigate these through effective risk registers or appropriate discussion and acknowledgement of risk where highlighted by internal staff.
- There was no system in place to assure the provider that care was delivered in a safe and effective way.
- There was no systematic approach to safety or improvement within the organisation. There was no effective governance process in place to monitor or learn from complaints, incidents or significant events. There was no formal record of incidents or complaints across all locations held at location or board level.
- There was no adherence to the fit and proper person's regulation despite this being introduced in 2015. At the time of our inspection, the provider was unable to provide evidence of a DBS check for one director. These were not all held on personnel records for all directors at the head office. We were provided with evidence of this DBS check following our inspection. There were no records of a formal recruitment process being carried out for appointed directors. One directors' personnel file we looked at did not include previous employer written references.There was no appraisal system in place for the directors.
- There was no system in place at provider or location level for collating the records of training, learning and development needs of all staff.
- There was not effective governance or monitoring processes in place to ensure that children and young people were safeguarded from abuse and improper treatment. The provider had not ensured a policy was in place in relation to female genital mutilation (FGM) and child sexual exploitation.
- There was a lack of understanding of the processes for obtaining patient consent to care and treatment in line with legislation and guidance.
- The provider did not have an effective process in place to enable monitoring of outcomes for patients or evidence of quality improvement. Quality improvement such as clinical audits did not take place however, we were informed this would be addressed.
- Practice specific policies were implemented and were available to all staff on-line. However, policies did not deliver consistency across the organisation and were not always being implemented and followed, for example in relation to infection control. The provider did not have a medicines management policy in place. It was not clear that policies and procedures were reviewed and updated regularly and the directors were unclear as to whether policies and procedures were current and that staff had read and understood them.

Are services well-led?

- The provider did not hold formal, structured, minuted meetings at either provider or location level. We were provided with some examples of board meeting minutes which were hand written notes and did not have standing agenda items for discussion. Meetings were either held informally or were ad-hoc. Staff we spoke with told us meetings at location level were not recorded.
- The provider had not ensured that a registered manager was in place at each location, at the time of our inspection only one out of seven locations had a registered manager in place. It is a requirement of registration with the Care Quality Commission where regulated activities are provided to have a registered manager in place.

Leadership, openness and transparency

On the day of inspection, the directors present told us they were aware of areas of concern which required addressing and discussed their plans to improve. However, there were no detailed or realistic plans in place to address these areas of concern. There was no documented business plan in place. We were not assured of the leadership, openness and transparency of the directors as no learning had been shared following concerns raised during previous inspections of other locations. For example, the Commission had inspected three locations during November and December 2016 all of which had multiple breaches. We were also informed during our inspection at the head office that Polmedics Limited – Allison Street, Birmingham, Polmedics Limited Bristol and Polmedics Limited – Wellingbrough locations were all closed that day. We were also informed that there was no electronic access to the appointments system for all locations from the head office. However, during our inspection we were able to access the appointments system and found evidence which showed that patients were booked in for appointments at all three locations that day, despite being told that Allison Street had not been re-opened to patients following the providers voluntary suspension of services due to lack of compliance with the regulations.

Culture within the service

There was no evidence of a safety improvement culture, the provider was unable to provide evidence to give assurance that systems and processes were in place across their areas of responsibility.

Fit and proper persons

Regulation 5 of the Health and Social Care Act 2008 Regulated Activities Regulations 2014 requires providers to ensure that all those with director level responsibility are fit and proper to carry out their role. Polmedics Ltd confirmed that at the time of our inspection they did not have a policy in place regarding the fit and proper person's regulation (FPPR). Without a formal policy in place, Polmedics Ltd was unable to demonstrate how it ensured its directors were fit to carry out their roles. During interviews, members of the board of directors stated that they were unaware of the fit and proper person regulation.

Furthermore, during a review of staff files held by Polmedics Ltd, we found that key documentation, which providers should ensure are acquired and available to the Commission under FPPR, was missing. For example, we were unable to see evidence of a DBS check, recruitment documentation or evidence of appropriate checks (including contacting the previous employer to inform suitability of employment) for one director. Evidence of this DBS check which had been issued in January 2017 was provided following our inspection. Staff files did not contain evidence to demonstrate searches of insolvency and bankruptcy registers had taken place.

Following a previous location inspection carried out in November 2016 and following the Commission's request for evidence of DBS checks for all doctors and dentists employed to work at Polmedics Limited – Allison Street, Birmingham, we were informed by the provider that a director who was a dentist had been suspended from duties by the provider due to having no DBS check in place at that time. This director was also under investigation by the GDC. We were informed that termination of appointment as a director had taken place in January 2017.

Learning and improvement

The directors present during our inspection did not give any assurance that there was a focus on continuous learning and improvement at all levels within the organisation. For example, the provider had not acted upon the same serious concerns which had already been raised during inspections of other locations during November and December 2016 where regulated activity was provided from. For example, concerns in relation to gaps in emergency medicines and equipment.

Are services well-led?

The provider had also been made aware of concerns in relation to the legibility of patient care records and the language in which they were written. We were provided with a revised policy dated 15 November 2016 in relation to patient care records. However, during further inspections at other locations, we noted that some patient care records were still written in Polish and were illegible.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Family planning services Maternity and midwifery services Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively to assess, monitor and improve the quality and safety of the services provided in the carrying out of the regulated activity. **How the regulation was not being met:** The provider had ineffective formal governance and leadership arrangements in place and did not have a programme of regular audit or quality improvement methods to assess, monitor and improve the quality and safety of the services provided. The provider did not ensure a system of clinical supervision/mentorship and clinical oversight was in place for all clinical staff including trainee dental nurses. There was a lack of effective systems and processes in place for identifying, assessing and monitoring risks including those relating to infection control, dealing with emergency situations, premises and equipment across all locations. The provider had not ensured adequate management and clinical leadership and oversight was in place on a daily basis at each location. Policies and procedures were not effective or consistently implemented and followed across all locations. There was no system in place to ensure all members of staff including directors had received an appraisal within the last 12 months. There was no system in place for collating the records of training, learning and development needs of staff.

This section is primarily information for the provider

Enforcement actions

There was no evidence of a system being in place for dissemination, reviewing and actioning NICE and MHRA alerts or evidence of any actions taken across all locations.

The provider did not ensure a record was held of Hepatitis B status for clinical members of staff who had direct contact with patients' blood for example through contact with sharps.

There was no formal meeting structure in place for multi-disciplinary or staff meetings at provider or location level.

During a review of staff files we found that key documentation, which providers must ensure are acquired and available to the Commission under FPPR, were missing.

The provider did not ensure that a system was in place within the organisation to ensure professional registration of clinical staff was routinely checked on an ongoing basis.

The provider did not ensure arrangements were in place to safeguard children and vulnerable adults from abuse and reflected relevant legislation and local requirements.

The provider did not ensure effective processes were in place for the timely reporting, recording, acting on and monitoring of significant events, incidents and near misses are in place across all locations.

The provider did not have an effective process in place across all locations to ensure patients were informed of their pathology results including those that were urgent or positive in a timely way or that they were assured that pathology results were disseminated and stored securely and patient information was protected.

This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.