Announced Inspection Report
26 November 2020

Day Lewis PLC

Type of Service: Independent Medical Agency (IMA)
Address: 2 Peterwood Way, Croydon, CR0 4UQ
Tel No: 077 0292 0967
Inspector: Stephen O'Connor

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

2.0 Profile of service

Day Lewis PLC is based in Croydon, England and operates community pharmacy and wholesale activities to a wide range of services. Day Lewis PLC is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent medical agency (IMA) with a private doctor (PD) category of care.

An IMA is an online medical service that can provide healthcare to patients through online consultations and through patient group directions (PGDs) provided in selected pharmacies.

The registration of Day Lewis PLC with RQIA was approved on 4 August 2020. Day Lewis PLC intends to offer a patient group direction (PGD) service to community pharmacists in Northern

Ireland (NI) who work with EMIS Health. EMIS Health supplies electronic patient record systems and software used in health care settings across the UK.

We evidenced that Day Lewis PLC have not yet commenced the provision of PGDs in NI and that they are actively working with EMIS Health to provide PGDs in the near future.

3.0 Service details

Organisation/Registered Provider: Day Lewis PLC **Responsible Individual:** Mr Peter Glover	**Registered Manager:** Mrs Rebecca Myers
Person in charge at the time of inspection: Mrs Rebecca Myers	**Date manager registered:** 04 August 2020
Categories of care: Independent Medical Agency (IMA) Private Doctor (PD)	

4.0 Inspection summary

We undertook an announced inspection on 26 November 2020 from 11:30 to 13:00 hours.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DoH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The purpose of the inspection was to assess progress with any areas for improvement identified since the last care inspection and to determine if the IMA was delivering safe, effective, and compassionate care and if the service was well led.

As previously discussed the agency is based in England and does not see patients face to face in Northern Ireland therefore all information regarding this inspection was submitted to RQIA electronically prior to the inspection. The self-assessment and supporting documents were submitted by the IMA within the agreed timeframe and reviewed on 24 November 2020 between the hours of 10:00 and 12:50.

We found evidence of good practice in relation to all four domains. These related to the monitoring and updating of the private doctor's details; staff training and development; the provision of information to patients allowing them to make an informed decision and engagement to enhance the patients' experience.

No immediate concerns were identified and we identified no areas of improvement during this inspection.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mrs Rebecca Meyers, Registered Manager as part of the inspection process and can be found in the main body of the report.

Enforcement action did not result from the findings of this inspection.

4.2 Action/enforcement taken following the most recent inspection dated 24 September 2019

Other than those actions detailed in the quality improvement plan (QIP) no further actions were required to be taken following the most recent inspection on 24 September 2019.

5.0 How we inspect

Prior to the inspection, a range of information relevant to the IMA was reviewed. This included the following records:

- notifiable events since the previous care inspection;
- the registration status of the establishment;
- written and verbal communication received since the previous care inspection;
- the returned QIP from the previous care inspection; and
- the previous care inspection report.

We invited staff to complete an electronic questionnaire prior to the inspection. No completed staff questionnaires were submitted to RQIA.

The agency is based in England, therefore as per an agreed RQIA protocol for the inspection of IMAs; the inspection was conducted in the offices of RQIA. A request for supporting documentation was forwarded to the provider prior to the inspection. The requested information was submitted to us electronically. Mrs Rebecca Meyers, Registered Manager was requested to be available for contact via the telephone on 26 November 2020, at an agreed time.

During the inspection, we spoke with, Mrs Rebecca Meyers, Registered Manager.

We examined records relating to the following areas:

- staffing;
- recruitment and selection;
- safeguarding;

- information provision;
- patient consultation;
- practising privileges;
- clinical records;
- patient group directions (PGDs); and
- management and governance arrangements.

Following a review of all the submitted documents, Mrs Rebecca Meyers, Registered Manager, was contacted at the conclusion of the inspection to discuss any issues and to provide feedback on the inspection findings.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 24 September 2019

The most recent inspection of Day Lewis PLC was an announced pre-registration inspection. The completed QIP was returned and approved by the inspector.

6.2 Review of areas for improvement from the last care inspection dated 24 September 2019

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for improvement 1 **Ref:** Regulation 19 (1) (a) (b) (c) **Stated:** First time	The applicant responsible individual shall ensure the following information is retained in respect for any private doctor working in Day Lewis PLC: • evidence of appropriate professional indemnity insurance; • confirmation that the medical practitioner has an appointed responsible officer; • evidence of completion of an annual appraisal; • evidence that the medical practitioner is trained and experienced in the type of treatment and services provided by Day Lewis PLC; and • evidence of continuing professional development and education in line with the requirements of the General Medical Council (GMC).	**Met**

	Confirmation of the above areas should be provided to RQIA upon return of the QIP.	
	Action taken as confirmed during the inspection: We evidenced that one private doctor works for Day Lewis PLC. Mrs Myers told us that a checklist has been developed which is subject to ongoing review and will ensure all information as specified within this area for improvement is retained. A copy of this checklist was submitted and reviewed prior to the inspection. We found the checklist included all relevant information. We also confirmed that all information in respect of the private doctor was submitted and reviewed prior to this inspection.	
Area for improvement 2 **Ref:** Regulation 19 **Stated:** First time	The applicant responsible individual shall ensure that a written agreement between the private doctor and Day Lewis PLC is put in place which sets out the terms and conditions of practising privileges and has been signed by both parties. Practising privileges agreements should be reviewed every two years.	**Met**
	Action taken as confirmed during the inspection: We evidenced that a practising privileges agreement was in place between the private doctor and Day Lewis PLC. We confirmed this agreement had been signed and dated by the private doctor and by Mr Peter Glover, Responsible Individual. Mrs Myers told us that practising privileges agreements will be reviewed at least every two years.	

Area for improvement 3 **Ref:** Regulation 15 (1) (b) **Stated:** First time	The applicant responsible individual shall ensure a pharmacist registered with The Pharmaceutical Society of Northern Ireland (PSNI) is one of the signatories in relation to the development and authorisation of each PGD.	**Met**
	Action taken as confirmed during the inspection: We confirmed that Mr Glover registered with the PSNI on 23 September 2020. Mrs Myers told us that Mr Glover will be a signatory for all PGDs developed.	
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (2014)		**Validation of compliance**
Area for improvement 1 **Ref**: Standard 14.1 **Stated:** First time	The applicant responsible individual shall provide RQIA with a copy of the policy for the recruitment and selection of staff which should include the requirement to have in place all documentation as outlined Schedule 2 of the Independent Healthcare Regulations (Northern Ireland) 2005, prior to commencement of employment.	**Met**
	Action taken as confirmed during the inspection: An electronic copy of the recruitment and selection policy entitled 'Staff recruitment policy' dated October 2020 was submitted prior to the inspection. We reviewed this policy and found that it fully reflected best practice guidance; the legislative framework and minimum standards for Independent Health Care providers.	

Area for improvement 2 **Ref**: Standard 11.1 **Stated:** First time	The applicant responsible individual person shall develop a policy and procedure which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.	**Met**
	Action taken as confirmed during the inspection: An electronic copy of the practicing privileges entitled 'Practising Privileges Policy (PGD Service only)' dated February 2020 was submitted prior to the inspection. We reviewed this policy and found that it fully reflected best practice guidance and outlined the procedure with respect to the application, granting, maintenance, suspension and withdrawal of practising privileges.	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

6.4.1 Staffing

Mrs Myers told us that there was sufficient staff in various roles to fulfil the needs of the agency and patients and that induction programme templates were in place relevant to specific roles within the agency. A Day Lewis PLC employee handbook was submitted prior to the inspection.

Through discussion and review of relevant documentation, we confirmed that there were rigorous systems in place for undertaking, recording, and monitoring all aspects of staff supervision, appraisal, and ongoing professional development.

We reviewed records and confirmed that there was a system in place to ensure that all staff received appropriate training to fulfil the duties of their role.

We established that Day Lewis PLC has one wholly private doctor. A doctor is considered to be wholly private if they do not have a substantive post in the NHS in Northern Ireland (NI) and are not on the General Practitioner (GP) performers list in NI. We reviewed the details of the private doctor and evidenced the following:

- confirmation of identity;
- current GMC registration;
- professional indemnity insurance;
- qualifications in line with services provided;
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC;
- ongoing annual appraisal by a trained medical appraiser;
- an appointed Responsible Officer (RO); and
- arrangements for revalidation with the GMC.

Mrs Myers told us the private doctor is aware of his responsibilities under GMC Good Medical Practice.

6.4.2 Recruitment and selection

The policy and procedure for the recruitment and selection of staff was reviewed prior to the inspection. We found the policy was comprehensive and reflected the recruitment journey and best practice guidance. As discussed there is only one private doctor involved with Day Lewis PLC. Personnel records for the private doctor were reviewed prior to the inspection and we confirmed that the personnel records included all information required under Regulation 19 (2) Schedule 2 of the Independent Healthcare Regulations (Northern Ireland) 2005.

Mrs Myers told us that all personnel recruited by Day Lewis PLC are subject to the recruitment policy and procedures. Our review of recruitment and selection procedures established that there was good practice in place regarding recruitment and selection procedures in line with legislative requirements.

6.4.3 Safeguarding

We reviewed the arrangements in place for safeguarding and found that policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The agency's safeguarding policies and procedures were provided to us prior to inspection and were found to be in accordance with the current regional guidance. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust (HSCT) should a safeguarding issue arise were included.

We confirmed that specific proposed PGDs will be available to children aged two and over.

Mrs Myers told us that all staff receive safeguarding training appropriate for their role. Training records submitted before the inspection evidenced that staff had completed training in safeguarding adults and children.

Our review of training records confirmed that the safeguarding lead had completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

6.4.4 Management of medical emergencies

As previously discussed Day Lewis PLC will not be offering face to face services to residents of NI and they have not yet commenced offering PGDs. Mrs Myers told us that the agency will ensure arrangements are in place for those pharmacists who will be providing PGDs to have an awareness of actions to be taken in the event of a medical emergency.

6.4.5 Infection prevention control (IPC)

Mrs Myers told us the agency will ensure arrangements are in place for those pharmacists who will be providing PGDs to have an awareness of IPC and that they adhere to regional guidance.

6.4.6 Patient group directions (PGD)

We confirmed that for each PGD there are governance arrangements with clear lines of responsibility and accountability and that PGD's are developed in accordance with The Human Medicines Regulations 2012.

Mrs Myers told us that all PGD's will be authorised by a Pharmacist registered with the Pharmaceutical Society of Northern Ireland (PSNI).

A number of proposed PGD's were provided by electronic mail prior to inspection. Review of these PGD's and discussion with Mrs Myers evidenced that a process is in place to ensure PGD's are updated in keeping with best practice guidance.

6.4.7 Risk Management

Mrs Myers told us that risk management procedures were in place to ensure that risks were identified, assessed, and managed. We confirmed the agency had a corporate risk register; this was a live document that was updated and amended as and when necessary. We reviewed records and confirmed that arrangements were in place to review the risk register and measures to mitigate and control the risks identified have been developed. We found measures to mitigate and control the risks identified have been developed with outcomes being monitored.

Areas of good practice: Is care safe?

We found examples of good practice in relation to monitoring and updating the private doctor's information; staff recruitment; induction; training; appraisal; safeguarding; and risk management.

Areas for improvement: Is care safe?

We identified no areas for improvement in relation to is safe care.

	Regulations	Standards
Areas for improvement	0	0

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

We reviewed the arrangements in place for the management of records to ensure records were managed and held in line with best practice guidance and legislative requirements. We reviewed a range of policies and procedures and found they included the arrangements regarding the creation, use, retention, storage, transfer, disposal of and access to records. We confirmed the agency had a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

We confirmed that in order for a community pharmacy to provide a PGD developed by Day Lewis PLC they must enter into an agreement with EMIS Health. This agreement specifies that they will use the Proscript Connect PMR software system provided by EMIS Health. Individual patient care records will be maintained by each individual pharmacy provider and the Day Lewis PLC does not have access to these patient records except if requested for investigation of an incident or complaint. We confirmed that anonymised patient records will be used for audit purposes.

Mrs Myers told us that all staff were aware of the importance of effective records management and records were held in line with best practice guidance and legislative requirements. Mrs Myers demonstrated a good knowledge of effective records management including maintaining patient confidentiality.

We reviewed records evidencing that there were systems in place to audit the completion of clinical records, develop an action plan if required and that the outcome of audits was reviewed through the agency's clinical governance structures.

We confirmed that information was available for patients on how to access their health records; in accordance with the General Data Protection Regulations May 2018 and that the agency was registered with the Information Commissioner's Office in England.

6.5.2 Communication

We reviewed information about the services provided by the agency and found that it accurately reflected the type of PGDs provided and was in line with GMC Good Medical Practice.

We confirmed the agency had a website that contained comprehensive information regarding the type of treatments provided. We found that the information provided to patients and/or their representatives was written in plain English.

Discussion with Mrs Myers and review of records confirmed that information provided to patients affords a transparent explanation of their condition and any treatment, investigation or procedure proposed. The information also includes any risks, complications, options and the expected outcome of the treatment or procedure. The costs of treatments were found to be up to date and include all aspects of the treatment.

Areas of good practice: Is care effective?

We found examples of good practice regarding the management of clinical records; the range and quality of audits; and ensuring effective communication between patients and staff.

Areas for improvement: Is care effective?

We identified no areas for improvement in relation to effective care.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

6.6.1 Dignity, respect and rights

Mrs Myers told us that the patient's dignity will be respected at all times during the consultation and treatment process and confirmed that the community pharmacy premises will be assessed for suitability for providing the service to patients. When a community pharmacy makes application through EMIS Health to provide PGDs the superintendent pharmacist must sign up to platform and declare that the environment is suitable to provide PGDs.

We confirmed through the above discussion that patients were treated per the DoH standards for Improving the Patient & Client Experience and legislative requirements for equality and rights.

We reviewed the arrangements in place to seek feedback from participating pharmacies and patients in relation to the quality of treatment provided, information and care received. We evidenced that Day Lewis PLC routinely seeks feedback from participating pharmacies and patients. Mrs Myers told us that information from satisfaction surveys is collated and reviewed by the management team. Mrs Myers confirmed that once operational in Northern Ireland, participating pharmacies will be included in the satisfaction surveys and that information received from patient feedback questionnaires will be collated into an annual summary report to be made available to patients and other interested parties to read online on the agency's website.

6.6.2 Informed Decision Making

We reviewed information regarding the services provided by the agency and confirmed it accurately reflected the types of services provided and was prepared in line with GMC Good Medical Practice. The information reviewed included the costs of treatment and is written in plain English. We found that the information provided to patients will enabled them to make informed decisions regarding their care and treatment.

6.6.3 Mental Capacity

Mrs Myers confirmed that it will be the responsibility of the Pharmacist to assess mental capacity. Should any concerns be identified in relation to mental capacity Mrs Myers confirmed that services would not be offered and the patient would be signposted to their GP.

Areas of good practice: Is care compassionate?

We found evidence of good practice regarding maintaining patient confidentiality; ensuring the core values of privacy and dignity were upheld; providing the relevant information to allow patients to make informed choices; and assessment of mental capacity.

Areas for improvement: Is care compassionate?

We identified no areas for improvement in relation to compassionate care.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

6.7.1 Management and governance arrangements

We examined various aspects of the governance systems in place and found there was a clear organisational structure within the agency. Mrs Myers told us staff were aware of their roles and responsibilities and of whom to speak to if they had a concern.

Where the business entity operating an agency is a corporate body or partnership or an individual owner who is not in day to day management of the practice, unannounced quality monitoring visits by the Registered Provider must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. We established that Mr Glover was in day to day charge of the agency, therefore the unannounced quality monitoring visits by the Registered Provider were not applicable.

6.7.2 Policies and procedures

We found that a range of policies and procedures were available to guide and inform staff. We confirmed that policies and procedures were indexed, dated and systematically reviewed at least every two years. We determined that Mrs Myers was aware of the policies and described how all staff have access to them. Arrangements were in place to review risk assessments.

6.7.3 Complaints management

We confirmed that the agency had a complaints policy and procedure in place and this was made available to patients/and or their representatives on the agency's website. Mrs Myers demonstrated good awareness of complaints management. As the service is not operational in NI we confirmed that no complaints had been received since the previous inspection. We were advised that complaints would be audited to identify patterns and trends and that any learning outcomes were shared with staff to improve the services delivered.

6.7.4 Management of notifiable events/incidents

We reviewed the arrangements in respect of the management of notifiable events/incidents and found that that no incidents requiring notification to RQIA had been identified since the previous inspection. We found that a robust incident management policy and procedure was in place to guide and inform staff.

6.7.5 Practising privileges

We reviewed the arrangements relating to the management of practising privileges. We confirmed that a practising privileges policy and procedure was in place which outlined the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges. We reviewed documentation and confirmed that there was a written agreement between the private doctor and Day Lewis PLC setting out the terms and conditions which had been signed by both parties during March 2020.

All doctors working within the agency must have designated Responsible Officer (RO). In accordance with the requirements of registration with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. Experienced senior doctors work as RO's with the GMC to make sure doctors are reviewing their work. As part of the revalidation process, RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has the responsibility to share this information with all relevant stakeholders in all areas of the doctor's work.

We established that the private doctor has a designated external RO. We found that good internal arrangements were in place and the agency was linked into the RO network.

6.7.6 Quality assurance

We reviewed the arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to patients; at appropriate intervals. If required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

We evidenced that a system was in place to ensure that urgent communications, safety alerts, and notices were reviewed, actioned and, where appropriate, promptly made available to key staff.

We found that arrangements were in place to monitor the competency and performance of all staff and report to the relevant professional bodies in accordance with their guidance. There were systems in place to check the registration status of all health care professionals with their appropriate professional bodies on an annual basis.

We found that a whistleblowing/raising concerns policy was available which provided help to staff to make a protected disclosure, should they need or wish to. Mrs Myers confirmed that staff knew who to contact should they have concerns or needed to discuss a whistleblowing matter.

Mrs Myers, Registered Manager, demonstrated a clear understanding of her role and responsibilities in accordance with legislation. Information requested by RQIA had been submitted within specified timeframes.

Mrs Myers told us that the statement of purpose and patient's guide will be kept under review, revised and updated when necessary and was available to patients on request.

We were informed the RQIA certificate of registration was up to date and displayed in the agency's offices.

We reviewed insurance documentation and confirmed that current insurance policies were in place.

Areas of good practice: Is the service well led?

We found examples of good practice regarding organisational and medical governance; management of complaints and incidents; and quality assurance.

Areas for improvement: Is the service well led?

We identified no areas for improvement in relation to the service being well led.

	Regulations	Standards
Areas for improvement	0	0

6.8 Staff views

We invited staff to complete an electronic questionnaire and no responses were received by RQIA.

7.0 Quality improvement plan (QIP)

We identified no areas for improvement during this inspection and a QIP is not required or included, as part of this inspection report.

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