

NURSE v SCHERING-PLOUGH

Alleged breach of confidentiality

A nurse complained about her suspension from a service provider in connection with an infusion service facilitation (ISF) nurse advisor programme carried out on behalf of Schering-Plough.

The complainant stated that she was suspended because she refused to give confidential information regarding her customers after the customers had signed confidential agreements. The complainant felt that her registration and code of conduct were being compromised and that this was against what the ABPI stood for. She had documentation and witness statements. This information was then going to be passed onto Schering-Plough.

The complainant explained that the programme was 'sold in' by the nurses who asked the consultant if they could review the unit and give feedback regarding staff and equipment etc used. This was for the unit to identify any issues and any changes needed to help increase efficacy for the patients and staff. This information was to be left on the unit and the only reports that went back to Schering-Plough were: number of units attended, number of introductory meetings, number of multi-disciplinary meetings completed and number of follow-up meetings.

At no time was any other information to be given to either the service provider or Schering-Plough (as per consent form).

Then the nurses were asked by their manager and the directors at the service provider to give all the information in the spreadsheets without the units' consent and a report would be given to Schering-Plough. (The complainant saw evidence of this report but did not have the documentation.) Six nurses resigned because their code of conduct was compromised and as the complainant spoke up for all of them and refused to give the information she was suspended but with backing from the Royal College of Nursing (RCN) she decided to resign rather than work for such an unethical company. The complainant submitted that she had never done anything like this before but felt so strongly for her customers and patients' confidentiality she felt she must make a stand.

The detailed response from Schering-Plough is given below.

The Panel noted that the intent of the programme was to benefit the NHS and maintain patient care by providing an assessment, service development and educational programme to support secondary care physicians with the care and management of patients receiving intravenous biologic therapies

within gastroenterology, rheumatology and dermatology. The unit agreement, which had to be signed by the ISF programme nurse advisor and the clinical director, or other authorised signatory, of the unit stated that '... the ISF Nurse will keep confidential all hospital and patient identifiable data to which he/she may have access during the provision of the ISF Programme'.

The Panel noted that the service provider had stated that, contrary to the complainant's submission, no other nurse advisor had resigned citing breaches of the Nursing and Midwifery Council (NMC) Code of Conduct as a reason. This company also submitted that the complainant was not suspended for refusing to supply confidential information in contravention of NMC Code or because she 'stood up' for colleagues in a similar position. The service provider further submitted that none of its nurse advisors had ever been required to disclose patient or unit identifiable data in contravention of any relevant codes or agreements with accepting NHS units. The Panel noted that there was a difference of opinion regarding the circumstances of the complainant's termination of employment.

The Panel noted that the agreement between Schering-Plough and the service provider was clear about the need to ensure that all confidential information was only disclosed to those who required the information for meeting the agreement and compliance with all applicable data privacy laws. The ISF Executive Summary made it clear that any associated data from the programme would only be reported to Schering-Plough in an aggregated, anonymised format with initial agreement from the participating unit. The service provider stated that it had, on occasion, received hospital identifiable data from nurse advisors but this was not required, requested or encouraged. There was no detail of any action taken by the service provider to remind nurses that the provision of such data was contrary to the unit agreement. The service provider stated that if it received hospital-identifiable data from the nurses then all reference to individual hospitals was removed before the data was stored. Hospital-identifiable or patient-identifiable data was never disclosed to Schering-Plough.

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The Panel considered that the allegation was a serious one; however it did not consider that evidence had been provided to show that on the balance of probabilities Schering-Plough had required data that would identify either hospitals or patients to be supplied. Thus the Panel ruled no breach of the Code.

A nurse complained about her suspension from a service provider in connection with an infusion service facilitation nurse adviser programme carried out on behalf of Schering-Plough Ltd.

COMPLAINT

The complainant stated that she was suspended because she refused to give confidential information regarding her customers after the customers had signed confidential agreements.

As a nurse the complainant felt that her registration and code of conduct were being compromised and that this was against what the ABPI stood for. She had documentation and witness statements.

This information was then going to be passed onto Schering-Plough.

The complainant explained that the programme was 'sold in' by the nurses who asked the consultant if they could review the unit and give feedback to the unit regarding staff and equipment etc used. This was for the unit to identify any issues and any changes needed to help increase efficacy for the patients and staff. This information was to be left on the unit and the only reports that went back to Schering-Plough were: number of units attended, number of introductory meetings, number of multi-disciplinary meetings completed and number of follow-up meetings.

At no time was any other information to be given to either the service provider or Schering-Plough (as per consent form).

Then the nurses were asked by their manager and the directors at the service provider to give all the information in the spreadsheets without the units' consent and a report would be given to Schering-Plough. (The complainant saw evidence of this report but did not have the documentation.) Six nurses resigned because their code of conduct was compromised and as the complainant spoke up for all of them and refused to give the information she was suspended but with backing from the Royal College of Nursing (RCN) she decided to resign rather than work for such an unethical company. The complainant submitted that she had never done anything like this before but felt so strongly for her customers and patients' confidentiality she felt she must make a stand.

When writing to Schering-Plough, the Authority asked it to respond in relation to Clauses 2, 9.1 and 18.4 of the 2006 Code of Practice.

RESPONSE

Schering-Plough stated that it had reviewed the documentation provided in the matter and took the view that it disclosed no breach of Clauses 2, 9.1

and 18.4 for the reasons set out below.

Schering-Plough explained that it had engaged an independent third party to provide defined services. The programme referred to was the 'Infusion Service Facilitation (ISF) Programme'.

Under the programme, the service provider's nurse advisors collected information about 'patient journeys' ie the experience of patients receiving infusions of biological medicines. The results from each unit were then used to identify potential areas for reducing bottlenecks in the process, thus enhancing the efficiency of NHS infusion services, and to improve the patients' experience of infusions. The intention was to improve the care and management of patients in accordance with local or national guidelines.

The ISF Programme was carried out by the nurse advisors who collected and collated information from specific units, typically infusion centres in hospitals and acted as facilitator for multi-disciplinary teams from the units concerned in reviewing the results of the analysis.

The services under the ISF Programme were based on Improvement Leaders' Guides on service redesign issued by the NHS Institute for Innovation and Improvement. Copies of the guides were provided.

The scope of the services provided were set out in the contract dated 12 December 2007. A redacted copy of the contract was provided.

The contract was entered into following negotiations between the service provider and Schering-Plough. Before signature, the contracts and the underlying ISF Programme were reviewed by internal and external lawyers and certified through Schering-Plough's formal certification process. Schering-Plough understood that a similar approval process was followed by the service provider.

Confidentiality was specifically dealt with in the programme documentation as follows:

- Clause 5 of the contract required compliance by both parties with data privacy laws and regulations. It also specified that neither party was permitted to transfer or otherwise make known *'the names or other personal data provided to it by the other party'*.
- A standard operating procedure (SOP) was included as an appendix to the contract, which regulated the manner in which the services were to be provided. In particular, the SOP specified at clause 7.2, that, *'[no] patient identifiable data will be collected...'*
- One of the template agreements relating to the SOP was the Unit Agreement. It was the only reference to hospital identifiable data in the programme. A copy of the unit agreement template was supplied by the complainant to the

Authority. This was an agreement entered into between the service provider and the unit before any services were provided under the programme. It specified that the nurse advisor would not have access to patient notes. It also specified that *'in accordance with the Data Protection Act 1998...'* the nurse advisor will *'keep confidential all hospital and patient identifiable data'*. Schering-Plough noted that the Data Protection Act 1998 only applied to personal data and did not extend to organisations. Despite that, it was clear that the parties intended that the names of the units involved in the programme would not be made public. Indeed, at no point were any details identifiable to any unit passed to Schering-Plough.

As the allegations related to activities undertaken on Schering-Plough's behalf by the service provider, Schering-Plough believed that its direct evidence in this matter was likely to be helpful. A summary of its key points in response to the complaint was provided. Schering-Plough believed that the summary clearly set out the position of Schering-Plough and the service provider on this matter. Schering-Plough also had the following comments:

- Schering-Plough was aware of the need to retain the anonymity of the units. Many units valued the assistance received under the programme and the opportunity to discuss the results with a view to identifying bottlenecks and potential improvements. However, it was felt that units would be less willing to take part in such a programme if poorly performing units were to be publicly named or if the results were to be presented in a competitive ranking. Likewise, if the programme were to be regarded by the units as a quasi-audit, they might inappropriately seek to 'improve' their outcomes, which could undermine the whole purpose of the programme. In view of that, it would not be in the interests of Schering-Plough or the service provider to record or disclose such details.
- The nurse advisors were trained on the ISF programme before its commencement. Part of that training related to the need for the nurse advisors to ensure that the unit agreements were signed before they carried out any services at the unit. As such, it would be the nurse advisor's obligation to anonymise the patient identifiable data and hospital identifiable data. Schering-Plough had never requested, seen or had access to any hospital identifiable data.
- Schering-Plough noted that the complaint related specifically to the alleged disclosure of the identity of the units concerned to the service provider and not patient identifiable data. Even if that allegation was true, which Schering-Plough denied, such information would not amount to 'personal data' under the Data Protection Act 1998. The Act defined 'personal data' as 'data which related to a *living individual* who could be identified – (a) from those data, or (b) from those

data and other information which was in the possession of, or was likely to come into the possession of, the data controller' (emphasis added). There was no breach of the provisions of the Act or of patient confidentiality and thus no breach of Clause 18.4.

Schering-Plough submitted that with reference to Clause 9.1, high standards had been maintained. The nurse advisors were trained on all aspects of the ISF programme, including obligations relating to confidentiality. The nurse advisors were aware of the need to anonymise data. If they failed to do so, the service provider would anonymise the data in any event, so no hospital identifiable data were recorded.

Under Clause 18.4, this was a programme which enhanced patient care or benefited the NHS and maintained patient care. It had been provided with due regard to Clause 18.1 and did not constitute an inducement to prescribe. The programme was not product related and sought to enhance patient care in a manner completely aligned with the NHS agenda.

With regard to Clause 2, programmes such as this were pivotal to enhancing the reputation of the industry with the NHS. No hospital identifiable data were disclosed to Schering-Plough. On that basis, there had been no breach of this clause.

Schering-Plough denied that there had been any breach of the Code or any data protection or privacy law. All the relevant provisions of the internal SOP had been followed by the service provider.

Schering-Plough noted that any grievance raised by the complainant and any disciplinary proceedings appeared to be purely an employment matter between the complainant and the service provider and were not ones which related to the Code, the law or Schering-Plough.

PANEL RULING

The Panel considered that as the service was provided as a medical or educational good or service the matter was subject to the Code. The intent of the programme was to benefit the NHS and maintain patient care by providing an assessment, service development and educational programme to support secondary care physicians with the care and management of patients receiving intravenous biologic therapies within gastroenterology, rheumatology and dermatology. The unit agreement, which had to be signed by the ISF programme nurse advisor and the clinical director, or other authorised signatory, of the unit stated that *'... the ISF Nurse will keep confidential all hospital and patient identifiable data to which he/she may have access during the provision of the ISF Programme'*.

The Panel noted that the service provider had stated

that, contrary to the complainant's submission, no other nurse advisor had resigned citing breaches of the Nursing and Midwifery Council (NMC) Code of Conduct as a reason. This company also submitted that the complainant was not suspended for refusing to supply confidential information in contravention of NMC Code or because she 'stood up' for colleagues in a similar position. The service provider further submitted that none of its nurse advisors had ever been required to disclose patient or unit identifiable data in contravention of any relevant codes or agreements with accepting NHS units. The Panel noted that there was a difference of opinion regarding the circumstances of the complainant's termination of employment.

The Panel noted that the agreement between Schering-Plough and the service provider supporting the ISF programme was clear about the need to ensure that all confidential information was only disclosed to those who required the information for meeting the agreement and compliance with all applicable data privacy laws. The ISF Executive Summary made it clear that any associated data from the programme would only be reported to Schering-Plough in an aggregated, anonymised format with initial agreement from the

participating unit. The service provider stated that it had, on occasion, received hospital identifiable data from nurse advisors but this was not required, requested or encouraged. There was no detail of any action taken by the service provider to remind nurses that the provision of such data was contrary to the unit agreement. The service provider stated that if it received hospital-identifiable data from the nurses then all reference to individual hospitals was removed before the data was stored. Hospital-identifiable or patient-identifiable data was never disclosed to Schering-Plough.

The Panel noted that the complainant had the burden of proving their complaint on the balance of probabilities. The Panel considered that the allegation was a serious one; however it did not consider that evidence had been provided to show that on the balance of probabilities Schering-Plough had required data that would identify either hospitals or patients to be supplied. Thus the Panel ruled no breach of Clauses 2, 9.1 and 18.4.

Complaint received **20 October 2008**

Case completed **23 December 2008**
