NHS EMPLOYEE v PROSTRAKAN

Osteoporosis review

An NHS employee complained that local practices had been misled to believe an osteoporosis therapy review service conducted by a third party service provider on behalf of ProStrakan was approved by the local clinical commissioning group (CCG) and was a continuation of the work done in 2009 when the CCG was a primary care trust (PCT). The complainant noted that the review appeared to be completely different to that done in 2009; the current review identified patients who had not ordered their calcium and vitamin D recently and switched them to non-formulary Adcal-D3 caplets.

The complainant remembered that ProStrakan had offered her another review via email but she had said no and it and had gone ahead despite the complainant not replying to another letter from ProStrakan offering such support.

The complainant noted that the protocol provided by one practice contained numerous inaccuracies and would never have been supported by the CCG. The complainant was further concerned that a company had deceptively gained entry to practices and access to patient records. The complainant saw this as a serious information governance breach bordering on fraud.

The detailed response from ProStrakan is given below.

The Panel noted the parties' accounts differed with regard to whether ProStrakan had misled practices into believing that the therapy review had been approved by the local CCG. The complainant had not been party to any of the conversations between ProStrakan, the third party service provider and the individual practices. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened. A complainant had the burden of proving their complaint on the balance of probabilities. The Panel noted, however, that a high degree of dissatisfaction was usually required before an individual was moved to submit a formal complaint.

The Panel noted that the complainant could not locate the email wherein she had declined ProStrakan's offer of a therapy review service and ProStrakan was unable to locate any such email or any other evidence that it had been informed that the CCG had adopted any position on the matter.

The Panel noted ProStrakan's submission that therapy reviews had only taken place after a detailed discussion with the practice concerned and with the written consent of two employees appropriately authorised to sign on the practice's behalf. The Panel noted ProStrakan's submission that local guidelines were often unavailable to those outside of a CCG and it therefore relied upon the individual practices to ensure that participation in the service was appropriate and acceptable. The Panel considered that conducting therapy review services at individual practices despite the CCG not having made a decision regarding a proposal or not wishing to undertake a project, was not in itself prohibited by the Code provided that the way in which it was done complied with all relevant requirements of the Code. If however, a CCG or similar had clearly not sanctioned such a service then it would not be unreasonable to expect a pharmaceutical company to make that clear when discussing the matter with relevant practices. The Panel noted ProStrakan's submission that none of its employees covering the territory or their line managers had been told that the CCG(s) had taken either a positive or negative position on the matter.

The Panel noted that two separate practices had informed the complainant that they had been led to believe that the CCG approved the service offered by ProStrakan. This was denied by ProStrakan. The Panel considered that to have two practices with the same misunderstanding was concerning however as a similar service had been locally approved in 2009 it was possible that the practices might have thought this service was a continuation of the previous service. Overall, the Panel did not consider that on the balance of probabilities the complainant had proved that either Prostrakan or the third party service provider had employed any subterfuge to gain access to individual practices by suggesting that the therapy review service now on offer was supported by the local CCG. The Panel thus ruled no breach of the Code. The Panel did not consider that the representatives had failed to maintain a high standard of ethical conduct and ruled no breach of the Code.

The Panel considered that the complaint was about misleading practices about the CCG's views about the service and not about the actual service provided to one of the practices. If the complainant was concerned about the actual service then a further complaint could be made.

The Panel noted its rulings above and did not consider that ProStrakan or the third party service provider working on its behalf had failed to maintain high standards. No breach of the Code was ruled including no breach of Clause 2.

An NHS employee complained about an osteoporosis therapy review service conducted by a third party service provider on behalf of ProStrakan Ltd. ProStrakan marketed Adcal-D3 (calcium carbonate/colecalciferol) caplets and tablets which were indicated as an adjunct to specific therapy for

osteoporosis and in situations requiring therapeutic supplementation of malnutrition and the prevention and treatment of calcium deficiency/vitamin D deficiency especially in the housebound and institutionalised elderly subjects.

COMPLAINT

The complainant explained that one of the local specialist pharmacy technicians informed her that a third party service provider had operated in local practices on behalf of ProStrakan. The practice manager from one surgery stated that the third party service provider had stated that the therapy review being offered was approved by the clinical commissioning group (CCG) and he/she had assumed that because the primary care trust (PCT) had done something similar in 2007-2009 it was OK and allowed them into the practice. A booking form provided showed that the activity had been going on since at least October 2013.

The complainant stated that the CCG had not supported the work and that any work would have had to go through its sponsorship panel and have, *inter alia*, a robust protocol, standard operating procedure, and letters to GPs introducing the project as it did in 2009, copies of which were provided. The complainant alleged that the company had misled practices into believing it was a continuation of the work done when it was a PCT whereas now it was a CCG.

The complainant provided a copy of the communication she sent to practices in the two CCG areas and posted on the pharmaceutical advisors group network. Following this communication, the practice manager at another centre, advised the complainant that it had been approached by the third party service provider which had stated that that it was a CCG supported project; a therapy review booked for May 2014 had since been cancelled.

A further practice notified the complainant that ProStrakan had approached it directly to offer the service like the one before.

The complainant contacted ProStrakan and the third party service provider. In response, ProStrakan stated that it and the third party service provider took such complaints very seriously; ProStrakan had made enquiries with the clinical director of the third party service provider and would speak to all of the relevant ProStrakan staff to seek clarity on what had been communicated with regard to the service. It was suggested that one of the senior managers meet with the complainant to have a more detailed discussion regarding her concerns. The complainant stated that she had responded and received a subsequent response from ProStrakan but did not wish to meet with ProStrakan at that stage.

The complainant reviewed her communication over the last year and found one letter from ProStrakan which she had not replied to. The complainant had asked ProStrakan for a comparison of Adcal-D3 with another named product which was the CCG's other choice on formulary. The complainant remembered that ProStrakan had offered her another review via email but she had said no. The complainant could not find that email but stated that had she agreed, the usual steps through the sponsorship panel would have been taken. The complainant noted that it could be seen from the final paragraph of ProStrakan's letter that it had offered support and had gone ahead despite the complainant not replying.

The complainant stated that one practice had only allowed the third party service provider in because it had been led to believe that it was a CCG supported project. The complainant noted that a protocol such as the one received from one practice would never be allowed, because, in the complainants view, it contained a number of inaccuracies including references to a PCT when these no longer existed, reference to content which was not provided and reference to Adcal-D3 caplets which were not on formulary. The complainant noted from a letter provided by one of the practices, it appeared to be a completely different type of review to the one done in 2009.

The complainant stated that she did not plan to meet ProStrakan or the third party service provider and that her complaint was on behalf of both CCGs.

The complainant was further concerned that her practices had been misled and a company had gained entry to practices and access to patient records. The complainant saw this as a serious information governance breach bordering on fraud.

ProStrakan was asked to respond in relation to Clauses 2, 9.1, 15.2, 15.3, 18.1 and 18.4 of the Code.

RESPONSE

ProStrakan submitted that it sponsored a therapy review service that was offered to all GP practices with computerised patient records and, as required by Clause 18, it was provided to any practice which expressed a desire to complete it. ProStrakan offered the service based on its current understanding of the new NHS structures; it could only be offered to, and authorised by, individual practices. ProStrakan encouraged CCGs to make recommendations with regard to the service but recognised that the decision and authority on such matters lay with each individual practice. Consequently its approach had always been based around invitations being issued to individual practices whilst seeking the approbation of other local authorities wherever possible. The third party provided the service to individual practices within the CCGs relevant to this complaint as a support to the local NHS. While the third party service provider was paid by ProStrakan, it was independent. The outcomes and documentation relating to the review belonged to the local NHS and were not shared with ProStrakan.

ProStrakan submitted that as GP practices were independent entities they might decide to undertake a review despite the CCG not having made a decision regarding a proposal or not wishing to undertake

a project. Reviews only took place following a detailed discussion of the protocol involved with the practice concerned and with written consent of two employees (either two GPs or a GP and practice manager). The protocol stipulated that the individuals signing on behalf of the practice must be appropriately authorised to do so. ProStrakan submitted that it was not aware that the CCG had decided not to conduct the project until it received the complaint. All interviewees were questioned at length regarding their discussions pertaining to the therapy review and the position of the CCG; all stated that they made no claims with respect to the views of the CCG neither did they believe that anything they said could have led to such a misunderstanding. The investigation uncovered no evidence to suggest that ProStrakan or the service provider had ever claimed that the service was CCG approved. Review of the documentation provided by the complainant and the additional documentation relating to the case found no evidence that such a claim had been made.

ProStrakan submitted that a key account team (KAT) worked principally in primary care and talked to health professionals such as GPs, practice managers and specialist nurses about three of ProStrakan's marketed products including Adcal. The KAT also discussed the ProStrakan therapy review service provided in accordance with Clause 18 at practice level. However, these discussions were conducted under strictly controlled conditions. KAT members were not permitted to discuss both promotional and non-promotional activities in the same call.

The detailed sales force briefing on the provision of the therapy review service was provided. ProStrakan summarised the key points.

The KAT was distinct from the clinical partnership team (CPT) which operated at a local health authority level (ie CCGs). The CPT might discuss therapy review services with appropriate members of a CCG with the view to encouraging participation in the interests of public health. The briefing document mentioned above also related to the CPT.

Only two ProStrakan employees were appointed to cover the aforementioned territory, a KAT and a CPT. Both were interviewed at length as were their line managers. None of the four had been told that the CCGs had taken either a positive or negative position on the matter.

Local discussions in relation to therapy review were practice-based and centred upon the protocol in order to ensure that all aspects of the service were open and transparent. ProStrakan was guided by the practice with respect to compliance with local procedures and policies. Local guidelines were often unavailable to those outside a CCG, ProStrakan therefore relied upon the individual practices to ensure that participation in the service was appropriate and acceptable.

The independent third party service provider was engaged by ProStrakan to undertake a therapy review service in line with Clause 18. The service aimed to facilitate the review of patients who might be at risk of osteoporosis using a practice-agreed protocol specifically designed in conjunction with each participating practice. The service was reviewed and certified in line with the Code, and was supplied in compliance with detailed briefing documents agreed with both parties. Relevant documents including an osteoporosis patient information leaflet and letter templates were provided.

From April 2013 reviews had been conducted in a number of practices across both CCGs.

ProStrakan submitted that the response to the Authority's question regarding the normal outcome of such audits depended on the definition of 'outcome'. The output of the review service itself, as defined by the protocol, were lists of patients who had been identified as being likely to be at risk of having, or developing, osteoporosis according to pre-agreed criteria. These lists were only seen by the third party service provider pharmacist and practice employees undertaking the review. All copies were kept by the practice, and any advice/treatment decisions made on the clinical judgement of the lead GP. The therapy review protocol had been

developed to ensure that the practice was in full control of the review and any subsequent actions.

If 'outcome' was related to the advice/treatment decisions that might be taken as a consequence of the review, ProStrakan could not comment, as all treatment decisions were kept strictly confidential. ProStrakan was given no information whatsoever on what clinical decisions had been reached. For the avoidance of doubt, ProStrakan noted that it was provided with no information with regard to clinical interventions resulting from a review.

ProStrakan submitted that a therapy review was provided to one of the surgeries named by the complainant following the consent of its practice manager and one of the doctors as was evidenced by the signed protocol provided by the complainant.

The practice manager alleged that he/she undertook the review as the third party service provider had stated that it was a CCG approved piece of work. The third party service provider employees covering this area were extensively questioned on this issue, but none were identified as the caller to which the practice manager referred. The third party service provider was contacted to establish whether any other employees from the company could have made the call. No other individuals were identified and it was not possible to establish that the third party service provider had made such a call.

In addition, in order to establish whether it might have been the ProStrakan representative on territory who contacted the practice, the KAT was also asked to clarify any and all contact he/she had had with the practice manager.

The only telephone contact occurred in the week before the therapy review took place. This call was made to ensure that the appropriate arrangements

were in place for the review the following week and without further detail on the call it was not possible to progress any further with this line of enquiry.

As requested, the documentation provided to practices undertaking a review had been provided which included a blank copy of the protocol used which specifically mentioned the services' standing in relation to local guidance. The section about medicine selection included a list of all marketed products in the therapy area. It was provided to ensure that all therapeutic choices were available and was not necessarily equitable to local formulary. This was specifically stated where the text clarified that the list provided: 'does not replace local guidance or protocols'.

The complainant had specifically noted one point in the document, stating that: 'this was entirely a pharma project not supported by CCG'. ProStrakan suggested that this section of the protocol had been slightly misunderstood. The intent of this passage was to establish the third party service provider's position as an organisation independent of ProStrakan and was not intended to establish any link to, or support by, the NHS.

During its investigation ProStrakan noted that there were errors in the documentation provided in relation to the review completed at one practice. The errors related to isolated instances where its internal policies had not been followed. Details were provided including ProStrakan's view as to whether the errors were or might be breaches of the Code.

ProStrakan submitted that it did not offer a switch service; it supported a therapy review service to facilitate the review of patients who might be at risk of osteoporosis using a practice-agreed protocol specifically designed in conjunction with each participating practice. No review would be undertaken without the express permission of two individuals within any given practice. The practice was in complete control of the progress of the review at all times and decisions for any intervention, including medication, were based on the clinical judgement of the authorising lead clinician.

In the emails associated with a proposed review at a second practice which was subsequently cancelled, the practice manager, alleged, that 'this company' contacted him/her claiming that the review was CCG approved, and that 'they were one of the last practices to be done'. The email did not clarify whether 'this company' was ProStrakan or the third party service provider.

The KAT contacted the centre in March 2014 and discussed the therapy review service with the practice manager and an audit by the third party service provider was booked. Despite repeated questioning on this issue the KAT was clear that no CCG involvement was mentioned or implied.

ProStrakan noted that an email from the medicines management project lead at one CCG related to communications the KAT had with an NHS employee. The KAT stated that he/she had met the NHS employee in April 2014 to discuss the therapy review service, and he/she expressed an interest in it. The KAT stated that he/she had mentioned that the project could be undertaken at CCG level, and that if the CCG was interested his/her colleague from the clinical partnership team would handle this.

The KAT denied that he/she had implied that the service was CCG authorised. Indeed, he/she recollected the NHS employee telling him to contact one of two individuals as he/she had not yet spoken to medicines management about it, neither of which had been contacted at the time of this response.

Having reviewed the letter provided by the complainant ProStrakan noted that the connection to the past project was made by the NHS employee, not the KAT. ProStrakan submitted that had the KAT already claimed that the project was CCG approved there would have been no need to establish to whom he/she should speak about having it signed off at this level.

ProStrakan wanted to address one of the medicine management employee's concerns that ProStrakan was trying to 'knobble the practices directly' by offering the service to individual practices. ProStrakan submitted that that was never its aim or intention and, as noted above, the Code required it to offer the service to any qualifying practice which wished to undertake it.

In conclusion ProStrakan submitted that despite having interviewed all ProStrakan and third party service provider employees covering the CCGs mentioned in the complaint it had identified no one who had claimed the project was CCG approved. ProStrakan had found no evidence that its representatives had acted in contravention to the Code in that regard and it denied a breach of Clause 15.3.

The therapy review service sponsored by ProStrakan was a medical and educational goods and service offered, and signed off, in line with the Code. ProStrakan provided the protocol, letters and briefing documents related to this service. It also interviewed all employees involved in the delivery of the service as identified by the complainant. ProStrakan submitted that it had identified no evidence that the service was offered in breach of the requirements of Clause 18.1.

Further to this, ProStrakan submitted that the documents supplied adequately clarified to the practices involved ProStrakan's involvement in the service and that of its provider.

ProStrakan submitted that it had found no evidence of ProStrakan or third party service provider employees acting in a manner that did not uphold the high standards expected of the industry. As it outlined above, ProStrakan had been unable to uncover any evidence that suggested either set of employees misrepresented the service with regards to CCG decisions. Indeed, it had not been possible to identify an employee of either company who was informed that a decision had been reached. The

service was offered to local practices in line with the guidance outlined by ProStrakan and the Code. ProStrakan did not consider that a breach of Clause 9.1 was warranted and consequently considered that a ruling of a breach of Clause 2 was not justified.

Regardless of the outcome of this complaint, ProStrakan apologised to the complainant for any inconvenience caused. ProStrakan submitted that it endeavoured to ensure that it worked with health professionals to improve patient care and to better the lives of patients treated with its products and was sorry that the complainant considered that it had not done so in this case.

In response to a request from the Panel for further information, ProStrakan submitted that a comprehensive review of the communications between the CPT and the complainant was conducted and only four emails were identified; three from the CPT to the complainant, and one from the complainant to the CPT, copies of which were provided. No communication informing ProStrakan of the CCG's position on the osteoporosis review service was identified during any of the documentation searches. Call reports from the customer record management (CRM) system provided no evidence which suggested that ProStrakan had claimed that the project was CCG approved.

ProStrakan submitted that following completion of the initial training program by the CPT, he/she started work on territory to contact key people within the CCG including the complainant. An email, sent to the complainant in July 2013, discussed how ProStrakan's osteoporosis therapy review service could assist CCGs to meet their local needs assessments. No response was received, and there was no further contact until the complainant emailed the CPT to ask about the price of products.

Following the complainant's email, the CPT tried a number of times to call and messages were left none of which were returned and the CPT was unable to secure a face-to-face meeting with the complainant.

Consequently the CPT replied to the complainant's email attaching the letter provided by the complainant in the original dossier which had been produced and certified for that purpose. Unfortunately, owing to the upcoming PPRS scheme he/she was unable to answer the complainant's question, so offered to get back in contact when able to fulfil the request.

As promised, the CPT sent a third email in February 2014. ProStrakan submitted that a meeting would have been preferred, but the complainant did not reply to the CPT's previous email.

During the week the complaint was received, the KAT told the CPT that he/she had received a voice message from the complainant who seemed to be displeased with ProStrakan and had concerns regarding the therapy review service.

As the complainant was at CCG level, the CPT took the lead in attempting to telephone the complainant to clarify the situation but was unable to reach her. Both KAT and CPT escalated the matter to ProStrakan senior management, who by this time had already been directly informed of the issues by the complainant.

As the CPT was going on holiday he/she contacted the KAT to update him/her on what could potentially be discussed should the complainant get in touch. However no actions were taken by either party as all communication was suspended pending an investigation into the complainant's concerns.

The complainant referred to an email that she sent to the CPT stating that the CCG did not wish to take part in a project relating to an osteoporosis therapy review but was unable to locate this email.

Having reviewed the records and correspondence from the CPT and the other parties requested by the Authority, ProStrakan could not locate any such email or any other written indication that ProStrakan had been informed that either CCG mentioned in the complaint had adopted any position on the matter.

ProStrakan submitted that on assuming the role from his/her predecessor, the CPT tried to contact the complainant to ensure that she knew ProStrakan would continue to support the CCG in whatever manner it considered appropriate. Much of the communication provided demonstrated ProStrakan's desire to work with the CCG according to its needs. The CPT conducted a considerable amount of background research into the priorities and objectives in this locality. Osteoporosis and falls were clearly part of the CCG agenda, and the CPT was consequently keen to discuss this with the complainant.

Unfortunately the opportunity to do this was not forthcoming, and the CPT was unable to secure an appointment with the complainant. The email provided was the only direct communication received from the complainant.

A thorough review of call records was conducted and ProStrakan could find no evidence to suggest that the service was offered as CCG approved. ProStrakan submitted that the term 'CCG' was used only twice in the records as follows:

- to refer to the institution for which the complainant worked.

- Call record of meeting held by the KAT and a practice manager which read 'Likes TR [Therapy Review] and will discuss with practice. Will also discuss with named CCG member, for implementation throughout a named CCG'.

It was during this meeting that the practice manager contacted the NHS employee, who was a member of the CCG board, to look for approval for the project at this level. ProStrakan submitted that the meeting with the NHS employee was discussed at length in its original letter but noted that the CPT would have no need to look for CCG approval if he/she

believed that it was already in place. Indeed the NHS employee, as a member of the CCG board, would be well aware of the status of the project, had any decision been taken.

ProStrakan submitted in conclusion, given the complexity of the complaint it was important to evaluate the documents provided above in light of the original issues identified.

ProStrakan submitted that the documents demonstrated that both ProStrakan employees named in the complaint were looking to discuss a CCG project because they had not yet received an indication that a decision had been made.

ProStrakan submitted that what had been demonstrated was its desire to work with the CCG, and to align its program if necessary to help meet local objectives. ProStrakan submitted that the CPT had conducted a considerable degree of research into the CCG's needs, and intended to present this to the appropriate individuals if given the opportunity. Supporting improved patient outcomes was a key part of the osteoporosis review service that it offered. ProStrakan submitted that in its experience, this was best achieved when it worked together with the CCG. Unfortunately this was not possible in this case.
ProStrakan submitted that overall it identified no evidence that the service was offered in breach of the requirements of Clause 18.1 and denied that this clause had been breached.

ProStrakan submitted that its representatives had upheld the standards required of them, and had not breached Clause 15.2.

Consequently ProStrakan refuted that a breach of Clause 9.1 was warranted, and therefore asserted that a ruling of a breach of Clause 2 was not justified in this instance.

PANEL RULING

The Panel noted the complainant's allegation that ProStrakan had misled practices into believing that the osteoporosis therapy review, offered by a third party service provider, had been approved by the local CCG. The Panel noted that the parties' accounts differed in this regard. The complainant had not been party to any of the conversations between ProStrakan, the third party service provider and the individual practices. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened. The introduction to the Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities. The Panel noted, however, that a high degree of dissatisfaction was usually required before an individual was moved to submit a formal complaint.

The Panel noted the complainant's submission that the CCG had not supported the work and that any work would have had to go through its sponsorship panel and have, *inter alia*, a robust protocol, standard operating procedure, and letters to general practitioners introducing the project as it did in 2009 when a similar review was undertaken. The complainant could not locate the email wherein she had declined ProStrakan's offer of a therapy review service and ProStrakan was unable to locate any such email or any other evidence that it had been informed that the CCG had adopted any position on the matter.

The Panel noted ProStrakan's submission that therapy reviews had only taken place following a detailed discussion of the protocol involved with the practice concerned and with the written consent of two employees who were required by the protocol to be appropriately authorised to sign on the practice's behalf. The Panel noted ProStrakan's submission that local guidelines were often unavailable to those outside of a CCG and it therefore relied upon the individual practices to ensure that participation in the service was appropriate and acceptable. The Panel considered that conducting therapy review services at individual practices despite the CCG not having made a decision regarding a proposal or not wishing to undertake a project, was not in itself prohibited by the Code provided that the way in which it was done complied with all relevant requirements of the Code. If however, a CCG or similar had issued a clear statement that the CCG had not sanctioned such a service then it would not be unreasonable to expect a pharmaceutical company to make that clear when discussing the matter with relevant practices. The Panel noted ProStrakan's submission that none of its employees covering the territory or their line managers had been told that the CCG(s) had taken either a positive or negative position on the matter.

The Panel noted that two separate practices had informed the complainant that they had been led to believe by the third party service provider that the CCG approved the service offered by ProStrakan. This was denied by ProStrakan. The Panel considered that to have two practices with the same misunderstanding was concerning however it noted that a similar service had been locally approved in 2009; it was possible that the practices might have thought this service was a continuation of the previous service. Overall, the Panel did not consider that on the balance of probabilities the complainant had proved that either Prostrakan or the third party service provider had employed any subterfuge to gain access to individual practices by suggesting that the therapy review service now on offer was supported by the local CCG. The Panel thus ruled no breach of Clause 15.3. Given its ruling regarding Clause 15.3, the Panel did not consider that the representatives had failed to maintain a high standard of ethical conduct. The Panel thus ruled no breach of Clause 15.2.

The Panel noted that the complainant referred to a number of errors in the protocol. The Panel was unsure whether the documentation was provided to support the complainant's view that the CCG would not have endorsed the ProStrakan service because it had concerns about its implementation or because the complainant was concerned about the service. The Panel considered that the complaint was about misleading practices about the CCG's views about

the service and not about the actual service provided to one of the practices. The Panel therefore did not make any ruling under Clause 18 of the Code. If the complainant was concerned about the actual service then a further complaint could be made.

The Panel noted its rulings above and did not consider that ProStrakan or the third party service provider working on its behalf had failed to maintain high standards. No breach of Clause 9.1 was ruled. The Panel thus ruled no breach of Clause 2.

Complaint received **9 April 2014**

Case completed **24 June 2014**
