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YEARS
LEADING
THE WAY

Duty of Co-operation Consultation on proposed regulations

Consultation Response

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The information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation

We are very happy for the contents of this response to be shared within the UK health departments and/or to be published in a summary of responses to this consultation.

We are responding on behalf of our health care professional members, principally doctors.

Profession:

We are responding principally on behalf of our members who are over 50% of the UK's doctors in hospital and primary care, and 30% of dentists. We also have nurse members and dental care professional members as well as other healthcare workers such as EMTs and our response covers them too.

Area of work:

MDU members work within the NHS and independent sectors and in a variety of other organisations where they provide professional services to patients.

Duty of Co-operation – Consultation on proposed regulations and draft accompanying guidance

PRELIMINARY COMMENTS

It is clear from the consultation document that these draft regulations are aimed principally at doctors. We have grave concerns about the regulations as currently drafted and believe they do not provide for fair process. We do not believe these regulations are the most effective way to enhance patient protection and it is possible that they may in part be detrimental to it. The whole tone of the consultation document is predicated on substantiating allegations, with the implicit premise being that by virtue of being voiced a concern can be substantiated; rather than explicitly requiring an allegation to be put to the healthcare professional involved and investigated through a demonstrably fair and transparent procedure before taking any appropriate action. This is entirely counter to the express intention of S121 (5) of the Health and Social Care Act 2008:

'In making regulations under this section the appropriate Minister must have regard to the importance of avoiding unfair prejudice to health care workers against whom unsubstantiated allegations are made.'

Because of our serious concerns about the potential adverse effect of these regulations on our medical members, we sought the advice of leading counsel whom we also asked to consider what legal remedies may be available in order to safeguard our members' interests. Counsel's advice is that the regulations as drafted do not set out reasonable steps to substantiate allegations. He advises that blatant disregard of reasonable steps to substantiate an allegation before disclosure could give rise to judicial review, which draft regulation 12 would not preclude. Further that if disclosure is not in accordance with regulations 6, 7 & 8 then this would not prohibit civil proceedings against the person making the disclosure, in spite of draft regulation 12. It is also leading counsel's view that the regulations as drafted may infringe healthcare workers' rights under the European Convention on Human Rights, principally Articles 6 & 8.

We believe our comments demonstrate that the introduction of a duty under these regulations would be far more costly than the impact assessment currently suggests, not least as the financial impact of potential legal challenges has not been considered.

We have never been persuaded that passing on information in the way proposed would add anything to the protection of patient safety, but we have made the point consistently that we believe it would considerably undermine the confidence of and in doctors and healthcare workers for no good reason. There are already effective mechanisms in place to provide information about doctors' performance – the GMC register provides immediate access to information about a doctor's fitness to practise history, and the alert letters system provide for exchange of information within the NHS. These draft regulations are unnecessary and will lead to the setting up of yet another procedure with far greater additional expense for the NHS, including substantial administrative and legal costs, than is envisaged in the impact assessment. However, if it is intended to pursue the regulations they must be redrafted substantially to comply specifically with the requirement in S121 (5) of the Health and Social Care Act 2008 and to comply with healthcare workers other legal rights as we set out in our response.

Consultation Questions

Q1 Do you believe that social workers provide services which are connected to health care, as defined in paragraph 2.7?

n/a

Q2 Do you agree that there is no need to designate the police in these regulations? See paragraph 2.16

Yes

Comments

It would be unnecessary and disproportionate to involve the police in every concern. There are already safeguards in place to ensure that healthcare workers who are suspected of having committed crimes are dealt with appropriately.

Q3 Do you have a view on whether we should designate HEIs so that they are subject to the duties of cooperation in respect of health care workers? See paragraph 2.19

No

Q4 Do you agree that Regulation 3 designates all those organisations that are connected to all health care workers involved in providing health care (which are not already designated by the Responsible Officers Regulations)?

No

Comments

If the principal intention of these regulations is to safeguard patients, regulation 3 is drafted too widely in that it could also cover all organisations that are connected with the provision of health care even though they have no direct involvement with patient care and their employees do not have any interaction with patients themselves and pose no risk to patients. If the intention is to protect patients, there is no need for these organisations to come within the scope of the regulations and they should be specifically excluded.

We have addressed estimated costs elsewhere in our response as our experience in medico-legal matters suggests that the estimated costs set out in the consultation document are unrealistic in that they are too low and do not properly anticipate the amount of work that will need to be undertaken and the considerable costs that will attract. Unrealistic costs are particularly relevant in respect of organisations that have no direct impact on patient care or whose employees have no contact with patients, even if those employees are healthcare workers. If the regulations retain the current wide definition of bodies that would have to comply, that would subject bodies to these regulations when there is no prospect of harm to patients, at disproportionate cost to them, and with no effect on patient safety.

We believe the scope of the regulations, in terms of the organisations they apply to, should be redrawn so that they relate more directly to protecting the safety of patients, which is the primary purpose.

Q5 If you answered No to Q4, which other organisations should be designated?

Comments

Please see our comments above. We do not think there is any need to designate other organisations, but there is a need to define the regulations more precisely to catch those organisations that have a direct relationship to care of patients and/or where their employees are providing patient care, so that organisations whose employees (even if they are qualified healthcare workers) have no contact with patients or whose work does not impact on patient care are excluded.

Q6 Do you have suggestions on what might usefully be included in the protocols or MoU to facilitate sharing of information about health care workers, between sectors? See paragraph 2.20

Yes

Comments

It must be clear in protocols that any information shared must be of some use to the organisation with whom it is shared. It would not assist the purposes of protecting patient safety to pass on information that is not verified and that consists merely of unsubstantiated allegations and/or suspicions. For the information to be of any practical use to the second organisation, it has to have substance and to have been tested through a fair process in order to provide the second body with accurate and reliable information it can act upon, if necessary, in order to protect patients or others.

Our main concern, confirmed by the advice of leading counsel, which we have also explained elsewhere in this response, is that the draft regulations as proposed have the potential to override the safeguards set out in the primary legislation to protect healthcare workers against unfair prejudice. The information that will be passed on has the potential (as it will always be considered as adverse by its nature) to adversely affect healthcare workers' ability to continue to practise in the short term, and perhaps their career in the longer term. The stated purpose of this document is to protect patients and that being the case, we do not understand why there is any suggestion that information may be passed on without having attempted to investigate it to determine if it has any merit, and without informing the healthcare worker to whom the information applies.

If there are valid concerns about patient safety, there are existing effective mechanisms in place to protect patients immediately such as informing the regulator and/or instigating existing disciplinary or performers' list procedure, and/or by telling the police if the matter may be criminal. In all such circumstances the healthcare worker would be subject to a procedure that would investigate and test the concerns and that could respond appropriately and swiftly if there are valid concerns about patient safety. To suggest that the legal protection of testing information through a fair procedure could be overridden because the relevant officer thought the healthcare worker in question might destroy evidence or put pressure on others is inappropriate. If that were the case, and these are very serious allegations for one person to make about another without having tested the evidence, and there were reasonable grounds for the relevant officer to have such concerns, the proper course of action would be to investigate the matter within the organisation in the first instance through the proper channels. This may mean invoking local disciplinary measures, such as exclusion or suspension where there are reasonable grounds, and the use of a statutory procedure would trigger protections for the healthcare worker, not least the involvement of an independent body such as NCAS. Patients would be protected, as would the subject of the allegations. However, if information were just passed on without testing it, and without the healthcare worker's knowledge, it would have no use to any other organisation. It would have no evidential value as far as their own procedures were concerned and would be merely unsubstantiated speculation or even gossip and not something on which any other organisation could take any action. It would in effect be the untested word of one person(s) against another.

To take a fictional example. Person A (who is relatively senior) suggests to the relevant officer that doctor B is falsifying his clinical audit information to cover up the actual number of patient deaths to make them seem far fewer than they are. Person A says that Doctor B is likely to destroy the evidence if these concerns are raised direct with him and that it may need to be investigated covertly. How would it serve patient safety if such a serious and unsubstantiated allegation was passed on to another organisation by the relevant officer before it was investigated and without doctor B being informed? It is a serious allegation but it may have no substance, and it would be of no use to any other organisation to have this information until it had been investigated, as the receiving organisation would not be in a position to do anything useful with it. Clearly the concerns would need careful investigation and the employing hospital might need to take urgent steps in the interests of patient safety. All of this must be done by the employing hospital. But if the information is passed on to another organisation without testing and without doctor B's knowledge, what is the second organisation supposed to do with it? If it were to start investigating doctor B's practice within that organisation or even exclude doctor B as a precautionary measure on the grounds of unsubstantiated information that had been passed on to it, it would have to tell him why and there would need to be reasonable grounds for such action.

Any protocols or MoU governing the passing on of information must make it a requirement that such information has been substantiated through proper investigation.

The protocols/MoU should also ensure that any information kept or shared is compliant with the Data Protection Act 1998. If there are concerns about doctor B, his employing hospital has a duty to investigate them in the appropriate manner and to take whatever action is appropriate to protect patients. If, at the end of that investigation, it is clear that there is a problem, then it may be necessary to pass on information to other organisations in which doctor B works. But if the allegations are investigated and have no substance, there is no need to pass anything on. Indeed it must not be passed on and the data must not be retained by the employing hospital. Stale information or a groundless allegation cannot serve any proper purpose.

Q7 What are the existing mechanisms in your organisation which the “relevant officer” could use for identifying and managing concerns about the conduct or performance of health care workers? See paragraph 2.26

Comments

Paragraph 2.26 and the question above suggest that, as well as identifying concerns, complaints procedures and serious untoward incidents recording procedures may also be used for managing concerns about the conduct or performance of health care workers. This is wrong. While such procedures may be of considerable use in identifying any concerns, if those concerns relate to an individual practitioner, there are existing locally agreed policies and procedures that should be used to investigate and manage those concerns such as Maintaining High Professional Standards for hospital trusts, and performers’ list procedures in primary care. And there is also the option of referral to the relevant healthcare regulator if appropriate.

Q8 Do you agree that one individual in an organisation should be given responsibility for complying with the organisation’s obligations under these proposed regulations?

No

Comments

In practice this will be an onerous task for one person and if the responsibility were in the hands of just one person there is considerable potential for a conflict of interest. How, for example, is it proposed that the procedure would address a concern expressed by a healthcare worker under scrutiny that there was a conflict of interest between the relevant officer and that healthcare worker that may call into question the fairness of any decision made by that relevant officer? The draft regulations for Responsible Officers recognise the potential for conflict of interest and the need for fairness where ROs are in a position to adversely influence the GMC registration and thus the ability to practise of doctors. However, mention of potential conflicts of interests is absent in these draft regulations. They should also recognise explicitly the potential for a relevant officer to have a conflict of interest and put in place statutory safeguards to ensure that the relevant person who makes a decision to pass on information that has the ability to affect the subject’s career adversely acts impartially and in a fair and reasonable way. This would be consistent with S121 (5) of the Act and the requirement to avoid unfair prejudice to healthcare workers against whom unsubstantiated allegations are made.

The consultation document does not make any stipulations about the procedures that should be used to investigate any concerns. We do not believe it can be taken as read that relevant procedures such as MHPS or performers’ list procedures should be used where they exist and this must be stated specifically in the regulations.

The regulations are wholly unclear and there is no specific guidance. In consequence it is not clear what procedures should be used in organisations where accepted local procedures and protocols do not apply, nor indeed that they must be followed in organisations where they do apply. Further it is not apparent what role the relevant officer will play in such organisations. All investigative procedures would need to be fair and robust, established, transparent, and nationally consistent. Given it cannot be the role of the relevant officer to set up such procedures, they will need to be satisfied that they are sufficiently robust to be in any position to rely on any decisions made about the accuracy or otherwise of allegations investigated in the interests of patient safety. In the absence of any nationally prescribed formula, ensuring there are such robust procedures in organisations where there are no existing agreed procedures will entail considerable resource implications in terms of the time taken by the relevant officer and in the additional support they may need if such procedures don’t exist already.

Beyond this, there is scope for legal challenge to decisions made by a relevant officer where there is no appeals process against any decision made by that person to share information or not to do so. It stands to reason that there may be more scope for challenging the reasonableness of a decision taken by one person, acting alone, without consultation with others. As currently drafted the regulations would allow for one person to make a decision to pass on information that is untested and unsubstantiated with potentially serious and adverse consequences for the healthcare worker to whom it relates. While Regulation 12 may be supposed to give some protection to that person acting in good faith, it does not rule out the potential for challenge by a healthcare worker who has been considerably disadvantaged by the actions of a relevant officer on the grounds that the person did not act reasonably and/or made a decision which is plainly flawed. We have referred later on in this response to leading counsel’s advice to us that there may be grounds for legal challenge remedies through the civil or administrative law, depending on the circumstances of the relevant officer’s actions.

We believe that the proposed regulations are considerably flawed and have been advised by leading counsel that they do not give sufficient protections to healthcare workers given the potentially serious and adverse consequences of the decision of a relevant officer to pass on information. It is likely that relevant officers may be the subject of repeated legal challenges from healthcare workers. And, it must follow that there is also the potential for legal challenge on the grounds that the relevant officer did not pass on information, where the relevant officer may equally be called upon to demonstrate that any decisions not to act were taken reasonably.

We have referred above to the need for some organisations that do not currently have locally agreed procedures and protocols for investigating and managing concerns to set up such procedures and to ensure they are robust and that they provide demonstrably fair decisions. For all of the reasons above we suggest that the impact assessment's cost benefits analysis, and specifically salary cost assumptions, opportunity costs and compliance costs are considerably flawed and vastly underestimate the actual cost of compliance with the regulations in terms of the work of relevant officers and of additional staff who will be needed to undertake all this work and to support the relevant officer. In addition the analysis of costs will also need to include an estimate of the cost of potential legal challenges and the impact that such challenges will have, especially on smaller organisations.

Q9 Do you think we should specify in guidance the minimum level of seniority a relevant officer should have? If Yes, what should that minimum level of seniority be?

Yes

Please see our comments immediately above. It is not for us to suggest the minimum level of seniority but the post holders will need to be persons whose skills and experience are of a level to enable them to understand often complex clinical information and legal concepts and to communicate effectively with all parties. They may be held accountable for their actions in a number of ways and should be senior members of staff who are capable of defending their actions and their decisions robustly.

Q10 How do you think the 'relevant officer' in your organisation might ensure that all the information in the organisation's possession is examined once the trigger (see flow chart at page 38) suggests a need for investigation or there is a request for information from another designated body?

Comments

There are a number of inaccuracies in the information in the paragraphs immediately preceding Question 10, as well as in the flow chart on page 38. The flow chart makes no mention of Maintaining High Professional Standards, the procedure that should be used for investigating and managing concerns about doctors and dentists in NHS trusts. In addition, it would seem to suggest that the performers' list procedures come into play only after information has been investigated, whereas in practice they are the appropriate means of investigating allegations and concerns, as well as for acting upon them. We point this out because these procedures are designed specifically to ensure that all relevant information is examined and that appropriate action is taken. In organisations where these procedures apply, the relevant officer should be able to rely upon this being carried out and should then be able to rely on the decisions reached. They should also be able to rely upon the agreed procedures that relate to investigations of healthcare workers other than doctors and dentists.

We believe the regulations must be revised to make it explicit that allegations must be investigated in a way that does not contravene other legal principles and duties on designated bodies. The investigative procedures must be fair and robust and give due weight to the rights of those who are subject to investigation under them. While it is intended that the relevant officer will need to rely upon decisions made as a result of these investigations, it would be entirely inappropriate for relevant officers to become involved in the procedures themselves. In the interests of fairness they must remain entirely independent of such procedures and have no influence over or interest in the investigations conducted and decisions made in respect of information they may have supplied.

The flowchart mentions GMC affiliates but does not refer to Responsible Officers. GMC affiliates will advise organisations, but not become involved in individual cases, whereas Responsible Officers will be involved in analysing information about doctors for whom they are directly responsible. The chart should also reflect the involvement of Responsible Officers.

Paragraph 2.29 suggests that relevant officers may wish to share information with healthcare regulators at a stage where the concerns about an individual practitioner do not call into question the fitness to practise of that practitioner, which is the regulator's threshold for taking action. If the intention here is to protect patients, this would be pointless. There is no merit in referring a practitioner to a regulator in the knowledge that there are not sufficient grounds for the regulator to take action. The appropriate course of action, in the interests of patient safety, would be to address the matter locally, through an appropriate procedure available to investigate the concerns and to take action as appropriate locally. (In the case of doctors, it is already noted at para 2.30 that the relevant officer could also liaise with the Responsible Officer.) If it turns out, after local investigation, that the concerns could potentially call a practitioner's fitness to practise into question, then it may be necessary to refer to the regulator at this stage, as well as taking any local action necessary to protect patients.

Paragraph 2.30 suggests that the relevant officer might check with a regulator if there is any relevant information on file. As far as the regulators of doctors and dentists are concerned, any information that they consider should be in the public domain, or be made available to employers on request, is already made available and any prudent employer would be expected to have checked before employing that doctor or dentist. If these regulators have an investigation ongoing, current employers are contacted and asked to contribute relevant information. It is hard to understand, therefore, why a relevant officer would wish to check with a regulator, as any information regulators have and can release is made readily and immediately available.

**Q11 Do you think guidance should set out any other responsibilities for the 'relevant officer' role?
See paragraph 2.28**

Yes

Comments

Paragraph 2.28 suggests that relevant officers should verify and/or investigate allegations. We have explained above that there are already statutory and locally agreed procedures and protocols in existence that must be used to conduct such investigations and to make determinations. In organisations that don't have such procedures, the relevant officer would need to ensure that these procedures are put in place, but for reasons of demonstrating independence of such procedures and their determinations, they should not be involved in the investigation or verification processes and nor in any determinations that are made.

It is telling that the responsibilities of relevant officers as set out at paragraph 2.28 are principally about protecting the relevant officer and that there is no explicit requirement to avoid unfair prejudice to the healthcare worker under scrutiny, as set out explicitly in the primary legislation. Further, the requirements do not set out the steps that should be followed in order to ensure the procedure is fair and without bias, acting upon the presumption of innocence that should be the right of anyone subject to such scrutiny. Words used in this paragraph, such as 'verifying' and 'substantiating' information do not convey the sense that concerns should be investigated with an open mind. Rather, they imply a presumption of validity. Any regulation that seeks to promote an investigation into a healthcare worker to substantiate an allegation, rather than impartially assess it (or ensure it was assessed impartially) would potentially contravene a number of legal principles and existing safeguards that protect healthcare workers. If this document were intending to describe a fair process, avoiding prejudice, it would use terminology that makes it clear that information provided may equally be inaccurate and/or without any substance, or indeed provided in bad faith. The responsibilities for relevant officers should be redrafted to reflect the fact that there should not be unfair prejudice to healthcare workers.

The procedure as outlined in the regulations and the consultation document does not set out many of the safeguards for healthcare workers such as the employer's duty to act reasonably and fairly and nor does it set out an employer's contractual duty to investigate complaints or allegations in accordance with the contract of employment and agreed disciplinary processes. Further, the documentation does not cover how these responsibilities will be assumed by the relevant officer or how that person will ensure such responsibilities are complied with. The steps as currently set out in 2.28 do not appear to provide for a fair and robust procedure that will provide adequate safeguards for the rights of the healthcare workers whose information may be disclosed and therefore, an appropriate procedure to demonstrate that relevant officers are acting in good faith. It is not for us to say how this paragraph should describe relevant officers' responsibilities but as currently set out they are inadequate and we believe they indicate bias against healthcare workers who will be subject to such procedures.

Q12 Do you believe the safeguarding measures will ensure that information about health care workers will be dealt with in an open and fair way? See paragraph 2.33 – 2.34

No

Comments

We have explained in our comments on paragraph 2.28 that we do not think that information will be dealt with in a fair way. There seems to be an assumption in that paragraph, and in the rest of the document, of a presumption that any concerns raised will be capable of verification and substantiation. While the motivation for introducing the new procedures has been explained, we believe it is misguided and based on false assumptions given there already are investigatory or disciplinary/contractual and alert procedures (which should protect patients if used appropriately) that are capable of working appropriately in order to address concerns and protect patients. Further the draft regulations and the guidance do not appear to take into account the need to test and prove in a fair and impartial manner serious allegations that have the potential, if proven, to end a doctor or dentist's current employment. The only likely outcome to that being, at the same time, the end of their medical or dental careers.

The examples given in paragraph 2.32 of circumstances in which information may need to be disclosed are all matters where the first steps taken by any employer that has concerns about patient safety must be to investigate these concerns. However, nowhere in this paragraph does it say that the most important action, in terms of protecting patient safety is to investigate the concerns as speedily and as thoroughly as possible and to consider if any immediate action needs to be taken while they are being investigated in the interests of protecting patients. It could potentially be detrimental to patient safety if relevant officers thought they had complied with their duty by sharing information with other organisations at the expense of investigating concerns in order to protect patients.

Only once the concerns have been investigated may it be appropriate to take any further action and that will depend on whether any concerns have been substantiated or are found to be without foundation. Thus the guidance in paragraph 2.32 should say, for example at (1) that it is only if the allegations, once they have been fully investigated, indicate that the healthcare worker poses a risk to patients or the general public that the designated body should consider whether it should pass on the information. Similarly the examples that follow are all of matters that are not yet determined and this guidance should be amended to make it clear that such information should only be considered for disclosure if it is proven, and not before. At (ii) it does not matter if the information comes from a reliable source and that it is supported by witnesses if, on investigation it is proven to be wrong. The fact that it comes from an apparently reliable source or that it is supported by witnesses is not justification enough for information to be disclosed unless it is proven that it gives grounds for concern. And, as we have described above, at (iii), there is no point passing on unsubstantiated information to any other organisation as it has no evidential value to that organisation, it cannot act upon it, and can do nothing with it unless and until it is substantiated.

There is no question that if a person makes allegations about a healthcare worker that raise concerns about the safety of patients or others, these concerns must be investigated immediately and thoroughly and appropriate steps taken by the employer/and or the regulator (depending on the seriousness of the allegations) to protect patients while any investigations are ongoing. However, it would serve no proper purpose in the interests of protecting patients to disclose information about the concerns to any other employer while such investigations are ongoing. If the concerns are serious enough to call into question that doctor's fitness to practise, they can and should be referred to the regulator at the same time as the first body investigates them. The regulator has powers to take any necessary and immediate action to protect patients and others while it investigates the matter, and before the facts are proven. This could include, for example, suspending a doctor's practice so he would not be able to work in any organisation pending the outcome of the regulator's investigation.

A second or third employer which may have received unsubstantiated information from the first does not have such powers. A second or third employer is not in a position to investigate the original allegations and cannot sensibly do anything with the information until it knows if it is correct, or it may equally be informed that it is unsubstantiated. If that second or third employer also has information about the same clinician's practice within that organisation that gives rise to concerns about patient safety, that employer should already be taking steps to investigate these concerns and to take any action necessary to protect patients. It should not be waiting until it receives unsubstantiated information from another employer that is irrelevant to its own procedures.

In all the circumstances above it is difficult to see how it would be anything other than detrimental to the interests of the healthcare worker for one organisation to disclose information to another organisation while an investigation was ongoing and, in some circumstances, without informing the subject of the information. It is equally difficult to see how this would improve patient safety.

In order to protect healthcare workers from unfair prejudice and to demonstrate that the intention is for healthcare workers to be treated in an open and fair way, consistent with their legal rights, we believe regulation 6 should be revised to specify clearly that investigations must be conducted. Sharing of groundless allegations would not protect the public and would not demonstrate that a healthcare worker was a threat to the health and safety of patients.

Q13 Are there any other safeguarding measures we should include in the regulations? If Yes, please specify what these are?

Yes

Regulation 6 (5) should be revised considerably to provide more appropriate protection for healthcare workers. It should be clear that only in exceptional cases should information be shared before informing the healthcare worker and seeking a response.

For our part, and especially where the primary consideration must be patient safety, we cannot think of any circumstance where it would be considered reasonable and in the public interest not to alert the subject to concerns and to allow him or her a chance to take part in any fair investigation. It is notable that paragraph 2.35 in the consultation suggests that information may be passed on in this way where there is a risk that the healthcare worker may try to interfere in any investigation or to destroy evidence. That this is a far less stringent safeguard than that of patient safety expressed in the draft regulations is a matter for concern. If there were reasonable grounds for concern and a belief that a healthcare worker might try to interfere with any investigation, there are already procedures to deal with this. For example, under MHPS, the healthcare worker could be excluded while an investigation took place. Using locally agreed procedures where they exist, or some other robust procedure such as referral to the regulator and/or the police if appropriate, would be enough to protect patient safety while the concerns were investigated. However, to pass on untested information at this stage would be of no use to any other body which would not be in a position to verify that information, or to disprove it, and thus would be unable to use it. It would serve no purpose other than to stigmatise the healthcare worker, unfairly as no allegations would have been proven.

This regulation as currently drafted overrides the intended protections for the healthcare workers that were put in the primary legislation and these regulations should not allow one person to pass on untried, possibly inaccurate and damaging information without any fair procedure to test it or to ensure its accuracy.

Draft regulation 6(5) should be amended to make it clear that only in exceptional cases should information be shared before informing the healthcare worker and getting a response. There should be a requirement for the relevant officer to satisfy him or herself that such uninvestigated and unsubstantiated information would be of use to the body to which it is sent in order to protect patients. Further that the purpose of protecting patients could not be more reasonably met by using locally agreed procedures, or referring to an appropriate body such as the police and/or a regulator to investigate concerns that posed such a threat to patient or public safety.

Q14 Do you agree that draft Regulation 6 provides a robust process for a designated body to substantiate an allegation against a health care worker before information based on it is shared with another designated body?

No

Comments

We have discussed our concerns about the process in part above in the section on the responsibilities of the relevant officer. The regulation as drafted makes no mention of the existing locally agreed and statutory procedures for the purpose of investigating and acting upon concerns about healthcare practitioners, yet the very minimum requirement must be that such procedures are followed where they exist. Most employers have contractual duties to investigate concerns in accordance with the contract of employment and agreed disciplinary processes, whereas the steps set out in the regulation provide no such process at all. They merely describe a limited number, but by no means all, of the steps that should be taken, and not the manner in which they should be done to ensure a fair and robust procedure. Further, the regulation does not

address the outcome of the process. For example the regulation does not touch on the employer's duty to act reasonably and fairly, the common law principles of natural justice in the conduct of investigations and disciplinary processes, the Article 6 right to a fair hearing, the need to process data fairly and lawfully etc. In organisations that do not already have contractual/locally agreed procedures and protocols the lack of detail in the regulations is an additional concern as it cannot be left to individual relevant officers to develop and implement such robust procedures and this is a serious omission.

We believe regulation 6 should be revised substantially, as should the guidance.

Q15 Do you agree that there is already robust guidance on how to handle confidential patient information? See paragraph 2.36 – 2.38. If No, please specify what additional clarification you need.

No

Comments

We cannot think of any circumstance in which it would be appropriate to override the Data Protection Act and the common law duty of confidentiality in order to pass on confidential information about patients either without their knowledge and consent, or even against their wishes.

We come back to the point we made previously about the purpose of the disclosure of the information. If there are concerns about a healthcare worker such that there are concerns about patient safety, those concerns must be investigated by the employing/contracting body and/or other relevant bodies such as the regulator or the police. All such organisations have in existence procedures in respect of maintaining confidentiality of patient information or statutory powers to require access to such information. While an investigation(s) is(are) ongoing, it would not serve any purpose to disclose the information to other organisations as they are not in a position to do anything about it, pending the outcome of the investigation(s) by the employer and/or others. In which case the need to disclose patient confidential information to another organisation does not arise. There is the further point that if identifiable information about a patient was passed on to another organisation without that person's consent, or even in spite of his or her refusal to give consent for its use, that information would be of little or no evidential value to the second organisation because the subject was either not aware of its use and should have been asked, or had expressly forbidden its disclosure to others.

We cannot see any justification for overriding patients' rights of confidentiality and would expect there would be potential for legal challenge if such disclosure were made.

Q16 When, in a recruitment process, does your organisation seek information/references about the conduct or performance of a health care worker? Does your organisation seek information from current or ex-employers prior to a request for a formal reference being made?

n/a

Q17 Do you think regulation 7 as it stands strike the right balance between the aims set out in paragraphs 2.46? Do you think we should provide in regulation 7 that designated bodies should only provide to a recruiting designated body information about a health care worker's conduct or performance prior to the stage where references are sought, where there is an immediate threat to patient safety (with regulation 7 being compiled with in full when the provision of references stage is reached)?

Unsure

Comments

Please see our earlier points about passing on unsubstantiated information. It would be inappropriate, misleading and potentially damaging to any healthcare worker for a current employer to pass on information that has not been substantiated. The prospective employer is not in a position to verify that information and can do nothing with it except draw adverse conclusions about the candidate at a stage where there is no proof of any concerns. We would expect that such actions may be open to legal challenge.

Q18 If a request for information about a health care worker is made by a designated body during an appointment process, should all the relevant clinical governance information held on file by the designated body receiving the request be transferred to the requesting designated body once the appointment process has been completed?

Unsure

Comments

That would depend on what is on file, consistent with employment law and the Data Protection Act. The actions of the current employer would need to be consistent with employment law and constitute a fair process. The current employer must not pass on any information that is unsubstantiated.

Q19 Do you foresee any difficulties with agreeing joint action where more than one designated body employs or contracts with a health care worker after one such designated body shares information under regulation 6(1) with the other designated bodies?

Yes

Comments

We are concerned at the suggestion in paragraph 2.50 that any new employer that becomes aware of a concern should check whether the previous employer has information relevant to the current concern with the new employer. If the regulations were in force, this should not be necessary because the original employer should have passed on any relevant substantiated information when the employee first moved jobs. The first employer should only pass on information that is verified and with the knowledge and agreement of the employee. If the first employer did not pass on any information, the likelihood is that there was no substantiated information to pass on and thus there will be no information upon request from the new employer.

Q20 What is current practice within your organisation about retaining information relating to verified allegations? See paragraph 2.61 – 2.62

Comments

Information about investigations and their outcomes should be retained in a manner that is consistent with employment law and the Data Protection Act 1998.

Q21 Do you have a view on retaining information for 5 years (or until completion of the next revalidation cycle if later) on allegations that are not possible to investigate fully or where the allegation is unfounded?

Yes

Comments

If it is not possible to investigate an allegation, and we can think of no reason why an allegation could not be investigated using existing/statutory procedures, there must be a presumption that the allegation is unfounded in the absence of information to substantiate it. If allegations are not investigated, and therefore not substantiated, or the allegations are proven to be unfounded, they must be destroyed in compliance with the 5th data protection principle that personal data processed for a purpose should be kept no longer than is necessary for that purpose.

Q22 Are you aware of any body, other than those listed above, whose guidance is of relevance to the proposed new regulations? If Yes, please specify.

Yes - NCAS

Q23 Are there issues on which guidance or clarification would help your organisation meet its obligations under these proposed regulations? See Paragraph 2.63 If Yes, what are those issues?

Yes

Comments

Organisations that are required to comply with the regulations will also need access to guidance on employment and data protection law and on a wide range of legal matters on an ad hoc basis as they arise in each case.

Q24 Do you agree with our estimate of the likely costs and benefits? See Impact Assessment. If not, please indicate and provide evidence, where possible, of any areas of disagreement.

No

Comment

We believe the costs of compliance with these regulations and of implementing fair procedures without unfair prejudice will be considerably higher than estimated. If the regulations are not amended as we have suggested elsewhere in our response, we have been advised there is scope for legal challenge on a number of grounds. The need to seek legal advice and the potential to be called upon to defend legal challenges should be built into any estimated costs. We believe other additional costs would include the provision of an appeals process and legal advice for that, the need to employ more than one relevant officer where the workload is too great, costs for setting up investigatory procedures in organisations where they do not currently exist and for training etc. We have covered all these matters elsewhere in our response.

Q25 According to the evidence presented in the IA, the likely cost of the preferred policy option on different organisations does not seem to be significantly related to their size. Do you agree with this proposition? If not, can you provide evidence to support your argument?

n/a

Q26 What might be the barriers (negative impact) to the proposed regulations "Duty of co-operation" and good quality outcomes for everyone from the perspective of ethnicity, gender, disability, age, sexual orientation, religion/belief, socioeconomic or rural/geographical considerations? What proportionate measures could address those issues? See Screening EQIA

n/a

Q27 What are the positive impact that might result from implementing this policy from the perspective of ethnicity, gender, disability, age, sexual orientation and religion/belief, socioeconomic or rural/geographical considerations? What proportionate measures might we implement that could enhance this positive affect?

n/a

Q28 Please identify how the implementation of this policy might affect the Human Rights of patients, carers, service providers or the workforce? In your opinion does this mean that this policy should not be implemented or could proportionate measures be taken to address these issues?

Yes

Comment

We have sought leading counsel's advice and his opinion is that the regulations as currently drafted potentially contravene a number of legal principles and existing safeguards that protect healthcare workers principally in respect of Articles 6 & 8. While we would support most initiatives that had as their purpose enhancement to the protection of patients, we believe we have demonstrated by our response to this consultation that the proposed regulations and policy, if implemented, would not enhance patient safety, and may in fact serve to obscure the proper protection of patients. For example, if there are concerns about a doctor it must be preferable to investigate them swiftly and thoroughly in the interests of protecting patients, than to pass them on untested to another body and to become bound up in legal challenges. While the express intention of the regulations is not stated as such, we believe we have demonstrated clearly that their practical effect if unchanged would be to stigmatise healthcare professionals if damaging information about them was passed on unsubstantiated and without their knowledge.

Q29 Do you have a view on the suggestion that local health care organisations should maintain a coherent and integrated set of information for all health care workers for whom the organisation which has clinical governance responsibility?

n/a

Q30 Do you agree that these categories of information are good indicators of performance or conduct? If not, please specify what other information should be included.

No

Q31 What concerns do you have about sharing "soft" information?

Comments

We believe we have outlined our concerns on this matter clearly elsewhere in this consultation response. We cannot envisage any circumstance where it could be argued successfully that it was reasonable, in the interests of protecting patients or the public, to pass on untested and potentially damaging information about a healthcare worker to another body without investigating the information in a fair and unprejudiced manner, and whether or not the healthcare worker is aware of this. The interests of patients and the public will always require that any concerns are swiftly investigated and that appropriate action is taken if proper investigation reveals there is reason for concern. We are advised by leading counsel that the regulations do not, yet should, provide protection for the healthcare worker who is a victim of a false allegation. This would preclude passing on information that has not even been verified.

Q32 Does your organisation already share "soft" information about health care workers? If Yes, please provide details.

No

Q33 Do you agree that contractors should notify PCTs of all negligence claims?

No

Comments

The MDU's view is that it is in the public interest, to prevent harm to patients and others, to identify poorly performing doctors as early as possible. This is best done by currently available means of identifying concerns at a local level and as early as possible. In the majority of cases it should be possible to remedy any problems at this stage, without the need to take more drastic action such as referral to the GMC or to begin disciplinary or performers' list procedures.

An effective monitoring system will need to include regular checks on doctors' performance, and analysis of whatever information they are required to provide. This can be achieved through a variety of tools such as regular peer review and audit, significant event analysis, appraisals and various other means. Our experience suggests it wrong to consider that claims against doctors are an indicator of poor performance; indeed it could be counter-productive to rely on such information, and in some cases work against the interests of patients who are suing for compensation.

Difficulty in defining what constitutes a claim

Many doctors may be involved in negligence claims as, for example, witnesses, experts, or because they were part of a team, but their own performance is never in question. It could not be construed in the public interest to inform a PCT of such peripheral involvement.

With claims against GPs, one of the first difficulties is that of defining at what stage, if any, claims could be reported to PCTs. Since Lord Woolf's reforms in 1999, the MDU's experience is that about 70% of claims our medical members notify to us are discontinued, usually before proceedings have been issued, though the figure is higher if you look at GP claims alone. The majority of these claims go no further than initial exchange of information in the pre-action phase, and it is clear from this that there has been no negligence. Often claimants' solicitors do not tell us that, having seen the relevant information, their client has decided not to pursue the matter. Therefore, it is not clear in many cases that they are not proceeding until they

become time barred (the limitation period runs for three years from the date of the incident or the date of knowledge, but could in any event be extended).

It would be unfair to require GPs to report notifications of claims to their PCT at a time when they are first received because the allegations are untested. We cannot see how it would serve any useful purpose as 70% of cases are not pursued, but this may not be clear until much later on, often only when they become time barred.

Most of the remaining 30% of claims are settled out of court, with no admission of liability. Very few cases go to trial and, in those that do; the judgement is usually in favour of the doctor. It is difficult to understand, therefore, if and at what stage a claim could or should be reported.

There are other equally persuasive reasons why claims are not a useful indicator of concerns about a doctor's performance.

Time lag

There is invariably a time lag between the date of an incident and the date a claim related to it is made. In general practice this happens, for example, with missed diagnoses or failures to diagnose which only become apparent much later, when further tests are done or the patient's illness becomes more severe. Seventy per cent of medical claims are notified to the MDU within three years of the incident, and the average settlement period for medical claims is 3-5 years after notification, though in complex cases it can be much longer. Where the patient is suffering from a mental disorder or disability, or where children are involved, the notification and the settlement periods can be much longer since there is either no limitation period, or it only begins to run when the child reaches 18.

If there are problems with a doctor's practice, it is important that they are identified as soon as they arise and addressed immediately. Given that on average settled claims take 6-8 years from the date of the incident to settlement, it could not be suggested that they provide any useful information about a doctor's current performance.

Purpose/aim of the clinical negligence procedure

The purpose of any investigation related to a claim is not to look at professional competence of any healthcare professionals involved, nor is it to decide what lessons can be learnt so that future incidents can be prevented. It is about establishing whether and how much financial compensation should be awarded to a patient who alleges he or she has been negligently damaged. The case is only concerned with whether there was a breach of duty and whether that breach caused the damage sustained by the patient. It is not concerned with establishing whether any healthcare professional involved in the care of the patient had any performance problems.

It should also be noted that claims are brought for a number of reasons that are outside a doctor's control. For example, there are certain areas in the UK that have a high rate of claims against doctors and others where there is a low rate of claims – the north west of England being an example of the first category and Scotland being an example of the second. This is unrelated to the competence or otherwise of doctors practising in those areas, but relates more to local factors such as willingness of patients to make a claim if something goes wrong, and the means by which they may fund a claim.

The incidence of claims is also affected by other factors such as the specialty of the doctor and the pre-existing conditions or expectations of patients. GPs may be deterred from taking on additional activities if they may find themselves at higher risk of claims because they are offering secondary care type services that are considered higher risk, such as fitting intra-uterine contraceptive devices and certain types of minor surgery. Again, the competence or otherwise of the doctor is not a factor in this higher risk.

Possible disincentive to settlement

Claims are settled for a number of reasons and many of them are not related to a doctor's performance. For example, an expert may say that the treatment was indeed reasonable but the notes are missing; or there may have been a time lag and those involved may have no reliable memory of events; the clinical issues may not be clear either way; or a non-negligent doctor may ask us to settle because he finds the prospect of going into the witness box too daunting and extremely disruptive to his professional and personal life. And, with vicarious liability, the mistake may have been made by a practice nurse, or receptionist but the claim might be made against and settled on behalf of the GP.

Currently when we settle claims we usually do so without an admission of liability on the doctor's behalf because cases are rarely so clear that they warrant such an admission. It is a question of balancing the pros and cons of each case and, through negotiation, reaching a position that is acceptable to both the doctor and claimant. We are concerned that if a doctor knew that he would have to report such a settlement to a current or prospective employer, and that it might harm his employment prospects, he may be reluctant to agree to do so. To continue to defend a claim may result in a long delay in its eventual settlement, or may mean that it is defended successfully and that the patient does not receive compensation. Either way, the legal costs of the claim will increase substantially. None of this is in the doctor's interests, nor is it in the interests of the patient who brings the claim, and who might otherwise have received compensation. To introduce such a disincentive would be damaging to both.

Q34 Do you agree with the definition of "claims"? If No, please explain why not?

No

Comments

A letter before action is far too early. In primary care and the independent sector around 70% of claims notified to the MDU do not progress any further. What purpose would it serve to be notified of the majority of claims that don't have sufficient merit to progress? We don't know what the figures are for claims against NHS bodies, and expect the number of claims not pursued may be fewer, but the claim is made against the institution and not the individual. The healthcare worker(s) concerned may know nothing about a claim where it is not pursued. Where there is a decision to settle or defend the claim, any healthcare worker(s) involved may disagree with a decision to settle on the grounds of expediency.

Time would be far better spent and it would better meet the duty of protecting patients to analyse other types of information that will provide a far more accurate and more immediate guide to concerns about doctors and others. Clinical negligence claims are a specialised field and PCTs have no knowledge of the claims process, nor can they be expected to have it. It would be of concern if information about claims was provided to them so that it could be used by their employees who are unfamiliar with the process and who may draw erroneous and potentially damaging conclusions about healthcare workers', especially doctors and dentists' performance, from claims data.

Q35 Do you support the above approach on sharing information with patients, carers, or the public about investigations?

No

Comments

The GMC register provides information about doctors under investigation and also about outcomes where there has been a fitness to practise procedure. This information is freely available on-line and by phone. Other regulators have similar arrangements and they provide all the information that should be in the public domain. What may be of interest to the public is not the same as what it is in the public interest to know. The provision of information about healthcare workers who are under investigation must be fair and not prejudicial and consistent with legal safeguards such as those in respect of confidentiality and employment rights.

We would not support information being available in any other format. If there are concerns about a healthcare worker's performance under investigation, it is a private contractual matter (and specified in MHPS) and should remain private. Even when there is an outcome, there is no right for anyone who is not directly involved in the matter or who does not have a demonstrable need to know to be made aware. It is of course important that patients, carers and others trust the procedures for investigating concerns and have faith in their outcomes, but not at the cost of breaching the employer's duty of confidentiality to its employee nor of stigmatising employees in an unfair and discriminatory manner.

Q36 Do you support the view that the national regulator should be alerted to a pattern of conduct or performance that falls below the threshold for referrals about fitness to practise?

No

Comments

Not automatically as it would depend on the case. As it is not possible to second guess what decision the GMC would reach, it is already possible to refer to the GMC in circumstances where it is not clear if a matter would amount to an adverse finding and sanction from an FTP panel. In such cases and where, after investigation, the GMC decides that the concerns fall short of a matter that would lead to erasure, but where it believes it is necessary and in the public interest to issue a warning, the GMC has had powers for the last 5 years to do so. That warning is placed on the doctor's record for 5 years and details are available on-line and to enquirers by phone during that time.

Q37 Are these examples of concerns about a health care worker's conduct or performance helpful to you when making decisions about how you would comply with the proposed regulations on duties of co-operation?

No

Comments

All of these concerns are allegations and they may only fall within these regulations if they are substantiated. Even if concerns are verified, considerable judgement will need to be exercised in order to ensure that it is reasonable to pass on information.

Some allegations on their own may not merit further investigation but those that do should be put to the individual in question, and investigated through a fair and transparent procedure if concerns are not allayed. There is still a presumption in law of innocence and it would be inappropriate to pass on information about any of these allegations unless they had been put to the healthcare worker and then investigated if that person could not allay any concerns. If they are substantiated, it would depend on the seriousness of the concern as to whether the information should then be passed on.

To give a couple of examples about the need to exercise judgement, if it was found that a doctor had breached confidentiality because he had spoken to a patient in a busy waiting room as there was nowhere else to speak to the patient and he needed to convey information urgently, surely the proper course of action would be to create a better place for doctors to conduct confidential conversations, rather than to pass on information about the findings in respect of that doctor. Similarly if a doctor had been coming in late and leaving early and, after investigation, it was established that this was because he or she had a very sick child/partner at home, it would be hoped that a more humane solution could be found, such as allowing the doctor to continue to work while ensuring that the sick child received appropriate care.

Q38 Do you have any additional comments on any aspect of this consultation?

Yes

It is clear from the consultation document that these draft regulations are aimed principally at doctors. We have grave concerns about the regulations as currently drafted and believe they do not provide for fair procedures. We do not believe these regulations are the most effective way to enhance patient protection and it is possible that they may in part be detrimental to it. The whole tone of the consultation document is predicated on substantiating allegations, with the implicit premise being that by virtue of being voiced, a concern can be substantiated; rather than explicitly requiring an allegation to be put to the healthcare professional involved and investigated through a demonstrably fair and transparent procedure before taking any action which may be appropriate. This is entirely counter to the expressed intention of S121 (5) of the Health and Social Care Act 2008:

'In making regulations under this section the appropriate Minister must have regard to the importance of avoiding unfair prejudice to health care workers against whom unsubstantiated allegations are made.'

Because of our serious concerns about the potential adverse effect of these regulations on our medical members, we sought the advice of leading counsel whom we also asked to consider what legal remedies may be available in order to safeguard our members' interests. Leading counsel's advice is that the regulations as drafted do not set out reasonable steps to substantiate allegations. He advises that blatant disregard of reasonable steps to substantiate an allegation before disclosure could give rise to judicial review, which draft regulation 12 would not preclude. Further that if disclosure is not in accordance with regulations 6, 7 & 8 then this would not prohibit civil proceedings against the person making the disclosure, even with draft regulation 12. It is also leading counsel's view that the regulations as drafted may infringe healthcare workers' rights under the European Convention on Human Rights, principally Articles 6 & 8.

We believe our comments demonstrate that the introduction of a duty under these regulations would be far more costly than the impact assessment currently suggests, not least as the financial impact of potential legal challenges has not been considered.

We have never been persuaded that passing on information in the way proposed would add anything to the protection of patient safety, but we have made the point consistently that we believe it would considerably undermine the confidence of and in doctors and healthcare workers for no good reason. There are already effective mechanisms in place to provide information about doctors' performance – the GMC register provides immediate access to information about a doctor's fitness to practise history, and the alert letters system provide for exchange of information within the NHS. These draft regulations are unnecessary and will lead to the setting up of yet another procedure with far greater additional expense, including substantial administrative and legal costs, than is envisaged in the impact assessment. However, if it is intended to pursue the regulations, they must be redrafted substantially to comply specifically with the requirement in S121 (5) of the Health and Social Care Act 2008 and to comply with healthcare workers other legal rights as we set out in our response.

We would be very happy to discuss our concerns in detail, including specific points from leading counsel's advice, though we are not able to share that with you in full.

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