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Bwrdd Iechyd Prifysgol
Bae Abertawe
Swansea Bay University
Health Board



Meeting Date	25 August 2020	Agenda Item	4.7
Report Title	Controlled Drugs Licence Requirement Policy		
Report Author	Patsy Roseblade (SBUHB - Corporate Governance)		
Report Sponsor	Judith Vincent		
Presented by	Judith Vincent		
Freedom of Information	Open		
Purpose of the Report	This paper provides assurance to the Quality & Safety Committee that this new policy has been developed according to Health Board process, it has been checked by a Barrister to ensure compliance with legislation, Welsh Government guidance and regulations. The paper has been discussed at and approved by the QSGG.		
Key Issues	The Health Board has been in dialogue with the Home Office with regards to the number and type of controlled drugs licences required since December 2016. The Health Board does not currently have a policy that covers the requirement for Home Office controlled drugs licences. This policy will now help to significantly mitigate the risk of having to purchase excessive numbers of controlled drugs licences.		
Specific Action Required <i>(please choose one only)</i>	Information	Discussion	Assurance
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Recommendations	Members are asked to: <ul style="list-style-type: none"> TAKE ASSURANCE THAT THIS POLICY HAS BEEN DEVELOPED IN LINE WITH HEALTH BOARD PROCESSES AND HAS BEEN EXTERNALLY ASSESSED FOR ACCURACY 		

CONTROLLED DRUGS LICENCE REQUIREMENTS POLICY

1. INTRODUCTION

This paper provides assurance that the new Controlled Drug (CD) policy has been 'approved' via the appropriate health board process and is fit for purpose.

An update on the licencing issues was provided to the Senior Leadership Team on 06 November 2019 with the final version of this policy being approved by the QSGG.

2. BACKGROUND

The Health Board has been in dialogue with the Home Office since December 2016 regarding the number and type of CD licences required. Given the extent of the number of licences required as suggested by the Home Office the Health Board sought legal advice via NHS Shared Services. This advice was disputed by the Home Office and as such the Health Board, again with the support of NHS Shared Services secured the advice of a Barrister. Given this is an issue that will affect all of the Health Boards in Wales, a contribution to some of the cost was made by all health boards.

Unfortunately the written advice provided by the Barrister included some misunderstandings of the healthcare provision which impact on the licence requirements. All of the misunderstandings were clarified at a meeting held with the Barrister in August 2018 but the Health Board only has its own notes of the meeting as opposed to an updated version of the Barrister's advice.

In order that a full understanding of the licencing requirements are understood by all clinical departments in the Health Board, and indeed Health Boards across Wales, the attached detailed policy document has been written. This policy has been reviewed by the Barrister who has confirmed, in writing, that it accurately reflects the legislation, regulations and Welsh Government guidance now in place. The policy will be used as a written record of the Health Board's position regarding licence requirements when dialogue with the Home Office re-commences.

As the outcome of the dialogue with the Home Office is very likely to be used as a precedent for all Health Boards in Wales, SBUHB has shared details of the health board and the Home Office positions to the Welsh Government Chief Pharmacist. Once this policy has been adopted by SBUHB the Medicines Management team, supported by the Corporate Directorate, will re-engage the Home Office with the intention of agreeing the licence requirements for the health board. It will also be shared with all Controlled Drugs Accountable Officers across Wales.

This policy was presented to the Quality and Safety Governance Group (QSGG) on Thursday 9 July 2020 where a few minor changes were suggested, all of which have been accepted and to policy updated to reflect this. The policy was subsequently approved by the Chair of QSGG and is presented here as the final step in the adoption process.

For ease of reference this policy will ultimately be appended to the over-arching controlled drug policy once the dialogue with the Home Office is complete.

3. GOVERNANCE AND RISK ISSUES

There are serious risks regarding the Home Office licence issues. The Barrister, in his original written advice, concludes the consequences of failing to have a correct licence differs depending on whether the issue concerns a Home Office controlled drugs licence obtainable under the Misuse of Drugs Act 1971 or a wholesaler dealer's licence obtainable under the Human Medicines Regulations 2012. The consequences for non-compliance in both cases, subject to proof of lack of knowledge, is a criminal offence punishable in extreme cases by imprisonment and/or fines, the severity of which depends on the classification of the controlled drugs in question.

As stated above, the Barrister has outlined the most severe punishment. The Health Board has **significantly mitigated** against the risk of this by voluntarily entering into dialogue with the Home Office albeit some time ago. However a follow-up email was sent to the contact in the Home Office in August 2019 for which a reply was received in February 2020. In response the draft policy was shared with the Home Office for which receipt was acknowledged but no further comments. It is also worth noting much of the official guidance relating to this issue is based on the English NHS as opposed to the NHS in devolved Nations. When liaising with the Home Office previously they have appeared unsure of how to interpret the rules in a way that relates to Wales and have needed to 'go away and consider the interpretation' coming back some weeks later with an answer.

Further mitigation includes the very detailed policy which includes the principle of the Home Office regulations with examples of implementation specific to SBUHB. As stated above this has now been confirmed as accurate by a Barrister.

This item is included on the Corporate Risk Register with a rating of 16 (rating 4 for impact and 4 for likelihood) with a target score of 8 (rating 4 for impact and 2 for likelihood). Following adoption of this policy this rating should be reduced to 12 (rating 4 for impact and 3 for likelihood). Once dialogue with the Home Office has been concluded and a licencing position agreed the item will have reached its target risk register score of 8.

4. FINANCIAL IMPLICATIONS

The initial cost of a Home Office possession controlled drug licence is currently £3,133 with the Wholesaler Dealer Authority supply licence being £3,655. There is then the annual 'maintenance' cost of the licence of £1,371 reduced to £326 if the Home Office decides an annual visit is not required. The Health Board will have no control over visiting decision.

In the early communications, the Home Office responded to queries with what appears to be a default position of 'licence required'. For example the health board asked a question about the 10 individual Learning Disability sites, the response from the Home Office has been a licence will be required for each site. Other examples include each EMRTS site, each community drug and alcohol centre and HMP Swansea.

This new policy includes in its examples all of the scenarios outlined above and in each case the view is a licence is not required. The health board currently holds the

controlled drugs licences it believes are required and therefore it is very unlikely there is a financial risk.

5. RECOMMENDATION

The Quality and Safety Committee are asked to take assurance that this policy has been developed in line with health board processes and has been externally assessed for accuracy.

Governance and Assurance		
Link to Enabling Objectives (please choose)	Supporting better health and wellbeing by actively promoting and empowering people to live well in resilient communities	
	Partnerships for Improving Health and Wellbeing	<input type="checkbox"/>
	Co-Production and Health Literacy	<input checked="" type="checkbox"/>
	Digitally Enabled Health and Wellbeing	<input type="checkbox"/>
	Deliver better care through excellent health and care services achieving the outcomes that matter most to people	
	Best Value Outcomes and High Quality Care	<input type="checkbox"/>
	Partnerships for Care	<input type="checkbox"/>
	Excellent Staff	<input type="checkbox"/>
	Digitally Enabled Care	<input type="checkbox"/>
	Outstanding Research, Innovation, Education and Learning	<input type="checkbox"/>
Health and Care Standards		
(please choose)	Staying Healthy	<input type="checkbox"/>
	Safe Care	<input type="checkbox"/>
	Effective Care	<input type="checkbox"/>
	Dignified Care	<input type="checkbox"/>
	Timely Care	<input type="checkbox"/>
	Individual Care	<input type="checkbox"/>
	Staff and Resources	<input checked="" type="checkbox"/>
Quality, Safety and Patient Experience		
Safety in the management of controlled drugs will be improved with a standard policy in place		
Financial Implications		
Without this policy in place the Health Board is in an exposed position with regards to the Home Office taking a stance that an expensive Home Office licence is required for multiple sites where controlled drugs are administered to patients. This policy, having been checked against the legal position by a Barrister, mitigates against this risk.		
Legal Implications (including equality and diversity assessment)		
As stated above, this policy has been checked for legal and Welsh Government guidelines compliance. The EQIA toolkit has been completed but, at the time of submission of this paper, there is no response to suggest a full EQIA assessment is required. Given the nature of the policy and the subject matter it is unlikely this policy will affect any group of people more than another.		
Staffing Implications		
This policy will enable staff to consistently apply the correct approach with regards to the requirement for a controlled drug licence		
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)		

Briefly identify how the paper will have an impact of the “The Well-being of Future Generations (Wales) Act 2015, 5 ways of working.

- **Long Term** – The Health Board, and indeed Health Boards across Wales, will be able to apply the complex rules regarding controlled drugs licence requirement consistently.
- **Prevention** – the risk of lengthy on-going dialogue with the Home Office should be reduced. .
- **Collaboration** – **this policy will be available to all Welsh Health Boards.**

Report History	This policy was presented to the Quality and Safety Governance Group (QSGG) on Thursday 9 July 2020 where a few minor changes were suggested, all of which have been accepted and to policy updated to reflect this. The policy was subsequently approved by the Chair of QSGG and is presented here as the final step in the adoption process.
Appendices	Appendix 1 - The Controlled Drugs Policy