The Company Chemists' Association response to:
WG Consultation on draft National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

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Contact details:

Paul Harris FRPharmS
Chair of Welsh Management Group, Company Chemists' Association
Company Chemists' Association Ltd
16 Upper Woburn Place
London
WC1H 0AF
Email: wmg@thecca.org.uk

www.thecca.org.uk

About the Company Chemists' Association. (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. Our membership includes ASDA, Boots, Lloyds Pharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate over 6,000 pharmacies, representing approximately 50% of the 717 pharmacies in Wales. Our members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing over 500 million NHS prescription items across the UK every year.

The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public. Our vision is that everyone, everywhere, can benefit from world class healthcare and wellbeing services provided by their community pharmacy.

Response

The CCA welcome the opportunity to respond the Welsh Governments consultation on draft **National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.** We believe this review of regulation is of tremendous value and extremely timely for community pharmacy as we work towards delivering a Healthier Wales.

Q1: Do you agree that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services for the purposes of the Regulations?

Yes.
However, we would request further clarity on whether the term "pharmaceutical services" will encompass essential, advanced and enhanced services.
We also wish to highlight a concern regarding variances and inconsistencies in commissioning by Local Health Boards (LHB). Sometimes LHBs will not commission all pharmacies within their footprint to deliver a Local Enhanced Service. Where this is the case, we would want the rationale to be clearly stated within the Pharmaceutical Needs Assessment (PNA), so that lack of provision from uncontracted pharmacies would not be perceived as a gap. We ask that our response to question 2 is considered for further context.

Q2: Do you agree that the health board should be placed under an obligation to consider all pharmaceutical services and are there any other persons providing those services that should be considered?

Yes.
We have some concerns around the use of the term "Pharmaceutical Services" being applied to both pharmacies and dispensing doctors within section 80 & 81. The term "Pharmaceutical Services" within section 81 implies that all pharmacy services, such as the Common Ailments Scheme (CAS) and the Emergency Medicines Supply (EMS) service could delivered by dispensing doctors. Whilst we realise this entry into

the pharmacy contract services arena may not be the intended consequence of the proposed regulation change this does provide a legally valid route. It may therefore be more appropriate to use a different term to refer to services provided by dispensing doctors such as “Dispensing services” a term that is used elsewhere within the regulation.

We would suggest that should the LHB commission services to pharmacy with similar alternatives being contracted to other providers, e.g. smoking cessation, these alternative services should be considered within the PNA.
We also note with some unease that there is no provision for conscientious objection within the regulations. This omission could create a circumstance whereby a pharmacist is in breach of the regulation if they choose not to provide a service as a result of their beliefs.

Q3: Do you believe there is anything that could be added to the list of required information to improve the content of a pharmaceutical needs assessment?

Yes. We believe there are several additions that would strengthen the regulation, including;

- When the PNA in initially written and each time the PNA is re-written within the 5-year cycle, there should be a full review of rurality. This will ensure the PNA is an accurate reflection of the gaps now presenting or of those that may have closed.
- The PNA should look to review dispensing doctor lists and it should state that this has occurred in each cycle and that actions have been taken to resolve any inaccuracies. This review will limit the risk of any patients remaining on or being moved to lists where there is no longer a need.
- We recognise that service availability at each pharmacy is constantly changing. These changes can lead to inaccuracies in the list held by Shared Services. We recommend that live and up to date LHB published lists of service provision are developed and these should be kept in the same location as the PNA. Any significant changes should prompt a supplementary statement. Please see our response to question 8 for further suggestion of how live status could be displayed across the NHS community pharmacy contractor estate.
- LHBs should clearly list their plans for any new services to be commissioned during the life cycle of the PNA.
- A full report (bilingual) from the LHB consultation phase must be provided to ensure this is a valued and acknowledged process detailing the changes made to the draft as a result of the consultation.
- The PNA should contain a list of ‘essential pharmacies’ across each LHB area. The closure of these essential pharmacies (potentially incurring market sanction) could be significantly detrimental to the local population and would automatically trigger a gap in provision, however we do not believe a full PNA re-write would be required.
- Similarly, areas of over provision should be identified within the PNA, which could then link into consolidation applications and applicants for PNA based relocations.

Q4: Is five years an appropriate interval between pharmaceutical needs assessments?

Yes. However, we believe the omission of the unforeseen benefits application route could cause some unintended consequences, for example if a pharmacy was to close within the five -year period and leave a gap not filled by other existing contractors, the unforeseen benefit option would allow new providers to apply if the newly proposed location is not within a given distance of current pharmacies.

Additionally, we are concerned with the suggested timescales for LHBs to complete the writing of the PNA once regulation comes into effect in April 2020.
In our experience from our members operating across the UK we are not aware of any PNA having been completed in less than 9 months and on most occasions, it has taken 12 months for this process and consultation to be completed. Producing a well-developed and accurate PNA will be critical, and we would not want to see this process rushed.

Q5: Do you agree the health board should be under a duty to revise its pharmaceutical needs assessment once it considers there are significant changes to the circumstances in its area; for example, when a large housing development takes place?

Yes.
However, we would caution LHBs to be precise and clear when wording the PNA's and we would welcome guidance for LHBs to support their consideration of what constitutes a significant change. An unintended consequence may arise where the definition of some words such as "gap" are not clearly defined within the PNA. We would expect any future needs identified to be specific to ensure the need is wholly met as part of the conditions of the granting of an application. We would also suggest that these gaps would need to be fully rationalised if they are contrary to the previous PNA.

Q6: Do you agree with the list of persons who must be consulted on the contents of an assessment?

Yes.
Community Pharmacy Wales (CPW) represents all contractors whereas there is more than one LMC representing GMS contractors. We would therefore suggest it may be helpful to include "Local Pharmaceutical Committees (LPCs) in neighbouring NHSE in border areas" and "Pharmacy contractors in neighbouring HB boundaries if affected" to be notified.

Q7: Are there any other persons who should be consulted?

Yes– see above question 6 – LPCs in neighbouring NHSE border areas and Pharmacy contractors in neighbouring LHB boundaries if affected.

Q8: Do you agree with the process for the health board's publishing of its assessment?

Yes.
In addition, we believe that LHB's should publish their PNA's online in an accessible area of their webpage this will make it simpler for contractors, NHS Wales and neighbouring LHBs or Clinical Commissioning Groups to find and use. It would also be extremely helpful to be able to locate and view any supplementary statements alongside the PNA which is not always the case in England and Scotland. Precision in completion and live status of these online versions is imperative and we ask that these resources should be maintained and updated by the LHB. We recommend further development of the choose pharmacy platform to support the live status of pharmacies.

Q9: Are there any other factors a health board should have regard to when making an assessment?

No,
But we believe the use of an all Wales PNA template and guidance on PNA development for LHBs is imperative to ensure consistency of approach that will help avoid too much variation across LHBs. Consistent data sources and metrics should be used by all LHBs to assess need to ensure outcomes are fair and equal across Wales.

Q10: Do you consider it appropriate to maintain existing pharmaceutical and dispensing doctor lists when the 2020 Regulations come into force?

Yes.
However, there is a risk of speculative applications so caution should be applied when draft PNA's are being prepared. Speculative applications have become problematic in England, especially where applications made against the draft PNA, assuming that the gap identified will remain in the final PNA. We do feel this is within the intended purpose of this regulation and we would suggest that all PNA's come into force on a specified date, and all applications are made against the PNA currently in place not against any new or updated PNA.

Q11: Do you agree to the maintaining of previously defined controlled areas?

No.
As previously answered, we believe that a full review of rurality on each occasion the PNA is written will ensure the PNA is an accurate reflection of the gaps now presenting or of those that may have closed.
We would also like to see a review of dispensing doctor lists, as this will limit the risk of any patients remaining on or being moved to lists where there is no longer a need.

We would also suggest it would be prudent of LHBs to publish comprehensive maps of these controlled localities within their PNAs, as any changes to the locality since the previous determination may give cause for a review.

Q12: Do you consider the change of test as a consequence of the introduction of pharmaceutical needs assessment to be appropriate?

No. We are concerned that the test is too restrictive, and we have looked to add further test criteria and detail within question 13.
We think it would be constructive if an application were to be granted, for all consultees to receive the detail around reasons for granting the application to enable a fair and even appeal process. Additionally, we call for a right of recourse from consultees to the LHB if the PNA contains factual inaccuracies upon which needs are assessed.

Q13: Are there any other criteria that should be applied to this test?

As previously mentioned, we believe this test to be too restrictive, however there are some additional test criteria that we feel would be helpful to add, including:

- **Deferred Applications** under certain circumstances such as a housing development being behind schedule, where an application is made too early or where the LHB is aware that another application is being submitted and they wish to consider both together.
- **Omission of timescales** for both LHBs to determine applications and Welsh minsters to process appeals. We recommend a timescale of maximum 4 months for each stage.
- **Unforeseen Benefits' application** should be included for situations when the PNA is in place but where a contractor believes a new need exists. We are concerned that the omission of this test could be seen as "anti-competitive" from the Competition and Markets Authority.
- **Competing applications,** we believe the regulation should describe in more detail the process for considering two or more competing applications made to fill the same gap.
- **Temporary pharmacy relocation regulation (21)** is too restrictive. It may not always be possible to return to the original premises (if damaged beyond repair) therefore we believe there should be an opportunity to return to the original site or relocate to new permanent site that is not necessarily the temporary relocation site.
- **Combine change of ownership and relocation application** this would reduce the time and duplication of efforts for contractor and Health Boards when considering these applications together.
- **Consolidation applications** should be considered for inclusion within the regulation.

Q14: Do you agree with the removal of minor relocations for premises?

No.
Regulation 19 permits a relocation only if the relocation still meets the need. An unintended consequence of the regulation could be that the PNA could inadvertently look to close a pharmacy in response to an application to relocate another pharmacy.

Furthermore, we suggest that minor relocations of less than 250 metres should be expediated and should not follow the same full consultation process.

Q15: Do you consider a move between health board areas should only be allowed when a need has been identified in the health board's assessment and providing it does not disadvantage access by persons accustomed to accessing services in the current location?

No.
It is unlikely that this provision will be used, however, we believe that the previous minor relocation regulation should be reintroduced with the addition of a permission which permits cross-border relocations. We believe a cross border relocation which doesn't materially change provision should be allowed for business need. In addition, we would suggest any considerations serving the same population should be consistent, either cross LHB borders or within an LHB boundary.

Q16: Do you have any comments to make on this consequential amendment?

No. We welcome this consequential amendment.

Q17: Do you have any comments on the criteria relating to inclusion in the list under specific conditions?

We are concerned Regulation 46 part 8 indicates that if an application is granted all core and supplementary hours would become core hours.
We would also like clarity regarding the use of the wording "additional hours" which does not align to the use of "supplementary hours" in other regulations.
We have some concerns surrounding the 3-year lock down period as this is unlikely to encourage existing contractors to participate in extended hours provision voluntarily, however for new contracts based on PNA gaps, we would be supportive.

In addition, there does not appear to be a paragraph 5 within Regulation 47(4) where it references paragraphs 4 and 5 and paragraph 4 is the same paragraph.

Q18: Do you have any comments in relation to local dispute resolution prior to the issuing of remedial notices?

Yes, we support the use of Local dispute resolution in the first instance. Further detailed guidance from WG around this subject will be vital for Health Boards to ensure that any concerns raised relate to a genuine issue and not an assumption or the result of hearsay.

Q19: Is there any other information a remedial notice should contain?

Yes, as previously described, detailed guidance and provision of expertise where necessary from WG around this will be paramount to ensure consistency of approach across LHBs.
There should be constructive dialogue between contractor and Health Board to resolve any disputes. We would not want to see the outcomes of the resolution process being unilaterally imposed upon the contractors by the LHB.

Q20: Are the terms under which the health board may withhold payment for a breach of services appropriate?

Yes, we partially agree. We believe WG should provide guidance on this issue in order to ensure consistency of approach and parity across all LHBs. We are concerned that there is currently the potential for inconsistencies in the sanctions applied across LHBs.

Q21: Do you have any comments about the process of remedial and breach notices?

No.

Q22: Do you have any comments on the criteria for removal from the pharmaceutical list in relation to performance matters?

Yes, we are not clear why there is no provision for suspension whilst awaiting completion of remedial action. There will be instances we believe where suspension would be more appropriate in advance of compliance to remedial action e.g. property maintenance.

Q23: Do you have any comments with regard to appealing health board decisions in relation to performance matters?

Yes, we expect the appeal process to be timely and able to deliver the benefit of change providing increased certainty for contractors as discussed in the consultation document. It would be unfortunate if any appeal process where to hinder this by being overly lengthy and arduous as has been experienced in the past.

Q24: Do you agree with this ‘stand still’ concept and these time scales?

Yes, but with some further points;

- As mentioned earlier in our response we do not believe LHBs will be able to complete the PNA process in time for use from October 2020.
- It must also be taken into consideration the length of time it will take to ensure that all documents comply with Welsh language standards. We are concerned that this will add significant time and complexity to the Health Board consultation process.
- We would like further clarification on how the six-month moratorium will apply for potential relocation applications (including temporary relocations). As Community Pharmacies in Wales have moved their focus to become more service based, we may begin to see an increase in the number of contractors looking to relocate, change premises or re-fit existing buildings to ensure their pharmacies are fit for purpose to deliver the community pharmacy services of the future. We have concerns with the introduction of the six-month moratorium for these potential relocation applications (including temporary relocations) as we believe this may become difficult to manage for contractors. Therefore, we seek further clarity on this proposal for existing pharmacies as the consultation intentions remains unclear
- We believe that the six-month moratorium should only apply to applications for new contracts.

Q25: Are there any unintended consequences created by the draft regulations you can foresee?

Yes.
There are several unintended consequences that we would like to raise.

- Our previous response to question 2 emphasised our concern with respect to developing Pharmaceutical services in section 81 to cover pharmacies and dispensing doctors. We are concerned that this change will allow dispensing doctors to provide the services currently provided by pharmacies, allowing access to funding from within the pharmacy global sum. Diverting NHS funding intended for pharmacy would not be acceptable unless there is a fair and equal opportunity for community pharmacies to obtain funding from other NHS sources such as the GMS contract.

- Additionally, we have concerns with regards regulation 46 as highlighted in our response to question 17. This regulation suggests that on granting of any application, all opening hours become core and there is a loss of the original core and supplementary hours split. This would be concerning for community pharmacies across Wales, as often business will be flexible with their opening hours in accordance to local need and their patient population. The burden of proof required to change hours within the current system can be excessive.

- A further concern is the lack of consistency on the Regulatory test for PNA based relocations within LHBs and across LHB areas. We suggest the criteria for being “not significantly less accessible” should apply to both relocation types and not just the cross LHB area. We believe it would be insufficient to

state that needs must not change across the whole LHB area as the impact would be most felt at a local population and cluster level and not necessarily across the whole LHB.

Q26: Are there any additional points you would like to make regarding the proposals set out in the draft regulations?

Yes, within the current Terms of Service requirements, we believe there are several requirements that are outdated and unnecessary and do not add to value to the contractor or the LHB who is monitoring the contract;

- **SOP requirements:** These are covered by GPhC regulatory requirements and so we believe this to be duplication and suggest removal.
- **Fitness to practice:** We would like to see a way of simplifying this request that would reduce duplication of the requirement to inform LHB's regarding a change of director and superintendent. The introduction of a home health board may assist in simplifying this requirement.
- **Core hours changes:** Currently contractors must prove changes to the needs of the people in the neighbourhood. We recommend this could this be changed to an application process highlighting why that contractor believes the change is needed (No alteration to supplementary hours change processes would be necessary).
- **Sign outside the pharmacy:** Currently a printed sign needs to be displayed when a pharmacy is closed to direct patients to another pharmacy. We suggest this could be removed as most relevant information is now available digitally - Google, NHS111, etc. Signs can go out of date very quickly. If this requirement remains, we recommend that the wording is changed to read "notify patients".
- **CPPQ:** We question the continuing need for CPPQ. We do not believe that the data provided is always constructive or useful for contractors or LHBs. We believe that CPPQ could be replaced with something that would add more value to patient care.
- **Audits**: The role of the practice-based audit and multi-disciplinary Health Board audit is now questionable given the number of audits carried out under the quality scheme. If still required could national audits replace local audit requirements in conjunction with CPW input as we believe this would offer more valuable outcomes to all. **Public Health campaigns**-we recommend a move to more generic participation in relevant public health campaigns agreed with the LPC/CPW.
- **Annual complaints report**: We question the continuing need for this annual report, and we can see no evidence that this data is reviewed or used by the LHB.
- **Clinical Governance Lead**: Again, we question whether this is still a relevant role to include within the regulation and we suggest it should be removed from requirements.
- **Induction for locums**: By providing an induction (detailed instructions) for off payroll workers (locums) Community Pharmacies are exerting 'control' meaning that they become 'employed' in the eyes of HMRC. This has significant tax liability consequences for both parties and so we strongly recommend using an alternative such as NESA/AWPD information to verify

locums working in Wales and to offer assurance that they can deliver services in Wales.

- **Charges for drugs and refunds**: This is still referenced in S5 (36) we would question if this is still required or whether the wording should be reviewed to reflect the zero-charge policy in Wales.
- **Provision of oxygen:** This is still referenced within the regulations this service has not been provided by pharmacy for some years, we call for its removal.

Others;

- **Serious Shortage Protocols (SSPs):** We are aware that the amendments have recently been laid in regulation which did not include a public consultation. We believe that this consultation should now take place and any amendments should then be finalised and included in these regulations.
- **Appliance contractor regulation**: We suggest the regulations do not reflect the service level expectation, we recommend the removal of some of the above requirements such as Clinical Health Board Audit and CPPQ as part of this review.

Q27: We would like to know your views on the effects that the draft regulations would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.

What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

We do not believe there would be any marked effects with regards the Welsh language.

28: Please also explain how you believe the proposed regulatory provisions could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.

We do not believe there is any necessary change required.

Q29: We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

We believe this valuable opportunity has been presented to transform the current system and Wales would be prudent to avoid the level of inconsistency that has been experienced within England though the introduction of PNA's.

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- We recommend that LHBs routinely review the PNAs of a neighbouring LHBs, thus enabling consistency of approach across boundaries for an entire PNA or

just where gaps may exist. This will ensure patient care is not compromised when moving through services from one Health Board to another.

- We believe in section S2(31)(g) requesting the name of the Responsible Pharmacist (RP) or the Superintendent Pharmacist would be more workable and appropriate, as the name of the RP may not be possible at the time of application.

- We ask for clarity around the securing of preliminary consent approval. For example: if the clock stops on the original application while the relocation application is being considered, this could potentially attract a new fee.

- We request further clarity on what would be considered as disproportionate for the LHB to not carry out a full PNA re-write as a result of changes in the localities. We suggest a definition for dipropionate needs to be provided.

Responses to this consultation will be made public in a report and published on the Welsh Government's website.

If you would prefer your response to remain anonymous, please tick here: