Explanatory Memorandum to *The Nurse Staffing Levels (Extension of Situations) (Wales) Regulations 2021*".

This Explanatory Memorandum has been prepared by the Office of the Chief Nursing Officer and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of *The Nurse Staffing Levels (Extension of Situations) (Wales) Regulations 2021*". I am satisfied that the benefits justify the likely costs.

Vaughan Gething
Minister for Health and Social Services
26 January 2021

PART I

1. Description

These regulations extend the section 25B duty (and its associated duties under sections 25C-E) under the Nurse Staffing Levels (Wales) Act 2016[1] to the additional situation of paediatric inpatient wards.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

None.

3. Legislative background

The Nurse Staffing Levels (Wales) Act 2016 ('the 2016 Act') received Royal Assent in March 2016 and inserted new Sections 25A to 25E into the National Health Service (Wales) Act 2006 ('the 2006 Act'). There has been a phased approach to its initial implementation in two parts.

The first duty under section 25A sets out the 'overarching responsibility' for local health boards and NHS trusts to ensure there are sufficient nurses to care for patients sensitively and applies to any setting where nursing care is provided including commissioned services. This duty came into force in April 2017.

The second duty under section 25B (and its associated duties within sections 25C-E) requires local health boards and NHS trusts to use a prescribed methodology to calculate and maintain the nurse staffing level for adult acute medical inpatient wards and adult acute surgical inpatient wards. This duty came into force in April 2018.

At the time the 2016 Act was passed, the decision was taken to apply the second duty to adult acute medical and surgical inpatient wards only as they were the only settings with an evidence base sufficiently developed to underpin the "*evidence-based workforce planning tool*", which the 2016 Act provides is necessary for calculating the appropriate nurse staffing level.

However, section 25B(3)(c) of the 2016 Act includes a regulation making power to extend the duty to calculate and maintain nurse staffing levels to other care situations.

The All Wales Nurse Staffing Programme ('the Programme') is currently driving the development of further evidence-based workforce planning tools, with four work-streams focussing on: adult mental health inpatient wards; health visitors; district nursing; and paediatric inpatient wards. The Welsh Levels of Care tool for paediatrics inpatients has been in development and testing since January 2018 and is now fit for use in ward settings. Therefore the section 25B duty to

calculate and maintain the nurse staffing level is being extended to paediatric inpatient wards in Wales.

These Regulations are being made under the draft affirmative resolution procedure.

4. Purpose and intended effect of the legislation

The purpose of these Regulations is to extend the duties in sections 25B - E of the Nurse Staffing Levels (Wales) Act 2016 (as inserted into the 2006 Act) to the additional situation of paediatric inpatient wards.

Namely, these duties are:

- 25B is the duty to calculate nurse staffing levels and to take all reasonable steps to maintain those levels. It also includes the duty to inform patients of those calculated levels.
- 25C is the duty to use a prescribed method of calculation for nurse staffing levels. This triangulated method uses: nurses' professional judgement; patient acuity through the evidence-based workforce planning tool; and nurse-sensitive quality indicator data.
- 25E is the duty to report every three years on the extent to which nurse staffing levels have been maintained on the wards to which these duties apply, and the impact that health board or trust considers that not maintaining those levels has had on care.

Section 25D places a duty on the Welsh Ministers to issue guidance about the duties under sections 25B and C, and how local health boards and NHS trusts are to comply with those requirements. The original statutory guidance document[2] published in October 2017 has been revised to include reference to paediatric inpatient wards and undergone a 13 week public consultation process.

The primary aim of these duties is ultimately to improve patient safety and quality of care in the clinical settings to which they apply. The available evidence (expanded in the RIA below) clearly indicates that having the appropriate number of registered nurses reduces morbidity, improves patient outcomes and saves bed-days. Having a standardised, evidence-based means of calculating what that appropriate levels of nursing staff is for each ward – accompanied by a statutory obligation to maintain those levels – will make it possible to articulate more clearly and consistently the staffing needs within paediatric inpatient wards and ensure the funding is made available by health boards and NHS trusts to meet those staffing needs.

The 2016 Act also ensures that the NHS more widely recognises the professional judgement of nurses in identifying how sick their patients are and their holistic care needs, and supports nurses from ward to board to have the necessary and sometimes difficult conversations about the resource requirements of their patients based on those clinical needs.

These Regulations will extend the scope of those aims to include paediatric inpatient wards and the young people treated on them.

5. Consultation

There is no statutory obligation to consult on regulations made under section 25B(3)(c) of the 2016 Act (as inserted into the 2006 Act). Therefore, there was no formal consultation on the Regulations themselves. However, the proposal to extend the duty to paediatric inpatient wards, and the consequent amendments to the statutory guidance, have been the subject of stakeholder engagement. The amended guidance was also subject to a 13 week consultation as explained below.

Section 25D stipulates that the Welsh Ministers must issue guidance about the duties under sections 25B and 25C (which supplement section 25B on the method of calculating nurse staffing levels). It also states that before issuing the guidance, the Welsh Ministers must conduct a formal public consultation process.

The original (current) statutory guidance was subject to a 12 week consultation in 2017. Amendments were required to the guidance to reflect the decision to extend the section 25B duty to paediatric inpatient wards. Before issuing the revised statutory guidance, another public consultation was required on the amendments made.

A 13-week consultation ran from 16 September 2020 to 16 December 2020 seeking views on the amendments that had been made to the guidance. The consultation was drawn to the attention of a wide audience of key stakeholders including Executive Nurse Directors, Chief Executives and Heads of Paediatric Nursing of each health board and NHS trust, the chairs of the All Wales Nurse Staffing Group and its key sub groups, the All Wales Senior Nurse Forum, the All Wales Ward Managers Forum, the Royal College of Nursing, the Nursing and Midwifery Council, youth patient groups, Community Health Council and the Childrens' Commissioner for Wales.

The consultation specifically sought views on the amended ward definitions, the list of ward exclusions, and the minor linguistic amendments that had been made throughout the document.

There was broad agreement to the revisions made to the statutory guidance document with a majority of respondents agreeing that the definitions were clear and easy to understand and that exclusions list was appropriate. A summary report of the consultation responses was published on 15 January 2021[3]. A small number of further minor revisions will be made to the statutory guidance based on respondents' observations, and the document will be published in spring 2021.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Options

Three options have been identified and are summarised here and referred to at various points throughout the document in terms of comparing the costs, risks and benefits of each.

Option 1: Status quo – Do not extend the section 25B duty to paediatric inpatient wards.

This option would mean no change to current practice as the section 25B duty would not apply to paediatric inpatient wards. In practice, this means health boards will continue to calculate staffing levels in those settings based largely on bed numbers and available resources rather than triangulating patient acuity, professional judgement and quality indicator data as prescribed by the 2016 Act.

Option 2:– Do not extend the section 25B duty to paediatric inpatient wards, but publish new non-statutory guidance to encourage health boards to use the 2016 Act's triangulated methodology for calculating more appropriate nurse staffing levels in paediatric inpatient wards.

This option would look to achieve as many of the benefits of the Act's second duty as possible to paediatric inpatient wards without enforcing it as a statutory obligation. As the evidence-based workforce planning tool for paediatric inpatient wards already exists, those wards could in theory practice the same triangulated methodology in calculating nurse staffing levels as has happened on adult acute medical and surgical wards for the last three years. This would have to be accompanied by non-statutory guidance to try to maintain a consistent approach across the different health boards.

Option 3: Extend the Act's second duty to paediatric inpatient wards through regulations

This option would use the powers granted by section 25B(3)(c) to extend the section 25B duty to calculate and maintain nurse staffing levels to paediatric inpatient wards in Wales through regulations.

This would put the same legal obligation on health boards and NHS trusts to calculate and maintain nurse staffing levels on paediatric inpatient wards as has applied to adult medical and surgical wards since April 2017. It also makes it a legal requirement to then publically report on the maintenance of those nurse staffing levels at the end of every three year reporting period.

7. Costs, risks and benefits

Costs

Option 1

This is the baseline option and as such there are no additional costs or benefits associated with this option.

Options 2 and 3

Additional staffing costs

Until the first triangulated calculations are undertaken on Wales' paediatric wards (which would likely take place in August/September 2021), it is not possible to say with absolute certainty what the cost to the NHS will be. This is due to the fact that the triangulated methodology takes into account actual ward data on acuity, quality indicators and the nurses' professional judgement on factors specific to their wards and staff. Indeed, the purpose of the 2016 Act is to provide staffing levels that more accurately reflect the patients' needs than fixed staffing ratios can.

However we have some sources of data that help us form an idea of an estimated range of cost. Prior to the 2016 Act passing through the Senedd in 2016, a similar Regulatory Impact Assessment[4] cost estimation exercise used a rough calculation based on several average variables applicable to adult medical and surgical wards established by NICE safe staffing guidance from 2014[5].

Those variables were:

Average nursing care hour needs per patient per 24h	5.32 hours
Average bed occupancy for an adult acute ward per 24h	30 patients
Average additional non-patient care workload per 24h	5.6 hours
Skill mix ratio	RN 65:35 HCSW
Number of hours worked by a full time equivalent nurse annually (37.5 hours per week x 52 weeks)	1950 hours
Number of acute patients in Wales per 24h (based on Stats Wales information from 2012)	7674 patients

By using these rough averages and nursing salary amounts from the time, a very broad estimate was calculated for the total cost of nursing staff to care for adult acute medical and surgical patients *safely*. Given the large number of adult wards, these broad average estimates were a pragmatic approach. There was also no comparison made to the funding for those wards at the time to give a sense of financial gap.

The above variables are mostly specific to adult care settings, and to use them for paediatric inpatient wards would not give an accurate picture of the estimated cost of this legislation. Currently there are no analogous NICE publications for paediatric inpatient wards, however it has been established through other reputable standards and guidance that paediatric patients require more care hours on average than their counterparts on adult acute wards.

With that in mind, we have used paediatric-specific variables from the RCN's *Defining Staffing Levels for Children and Young People's Services* guidance[6] for our calculations.

We have also been able to use more relevant data for our paediatric inpatient wards rather than applying a single average for all. This is due in part because of the far smaller number of wards compared to adult acute wards, and also because of the health boards' data returns on the Chief Nursing Officer's interim paediatric nurse staffing principles.

In July 2019, the Chief Nursing Officer published a set of interim nurse staffing principles for paediatric inpatient wards, following the model established by the adult medical and surgical interim principles (2012) and then the district nursing interim principles (2017). The principles were largely informed by the above-mentioned RCN guidelines.

The purpose of these principles was to:

- establish a detailed baseline picture of the existing nursing workforce in our paediatric inpatient wards;
- identify the resource gap between the current position and full compliance with those principles; and
- close that gap over time with gradually increasing compliance to lessen the impact to the system if/when the 2016 Act's second duty is implemented to paediatrics inpatient areas.

There are some important caveats to bear in mind when considering the data submitted thus far by health boards on their compliance with the principles:

- the audits take place over a single week per data-capture exercise and comprise two measures per calendar day (day shift and late shift), meaning the sample size from each return is fairly limited and not necessarily reflective of demand throughout the year;
- the Covid19 pandemic interrupted the second audit exercise of compliance with these principles in March 2020, therefore we only have data for November 2019 and November 2020. This means the overall sample size is also very limited;
- the demand on paediatric inpatient services has seen a notable decrease since the Covid19 pandemic, and thus the November 2019 data is likely to be more reflective of "normal" demand going into the future than the November 2020 data;

- the data returned by health boards is not rigorously verified and is therefore open to human error; and
- bed occupancy levels in paediatric inpatient wards are more prone to frequent fluctuation than adult acute inpatient wards.

With that in mind, the returned data still helps to paint a picture of the nurse staffing landscape in Wales' paediatric inpatient wards and inform thinking around potential cost to the NHS.

The variables used in this costing exercise are as follows:

Average RN nursing care hour needs per patient per 24h (based on 1:4 ratio suggested by RCN's guidance).	6 hours
Average peak bed occupancy for each paediatric inpatient ward i.e. the mean average of the occupancy high point on each shift over the course of the available data period (based on ward-specific data submitted by health boards, attached at **Annex 1**).	Varies according to ward
100% bed occupancy rate (based on ward-specific data submitted by health boards, attached at **Annex 1**).	Varies according to ward
Skill mix ratio (as per ratio suggested by RCN's guidance).	RN 70:30 HCSW
Number of hours worked by a full time equivalent nurse annually (37.5 hours per week x 52 weeks).	1950
The addition of 26.9% uplift added to all RN and HCSW costs (as per the requirement in the 2016 Act's statutory guidance)	Varies according to individual costs
The addition of a supernumerary band 7 ward manager (as per the requirement in the 2016 Act's statutory guidance).	£57,853 per ward
Existing funded RN and HCSW establishments (based on ward-specific data submitted by health boards).	Varies according to ward
Annual salary of band 7 RN based on high-point of scale + 30% NHS on-costs	£57,853
Annual salary of band 5 RN based on mid-point of scale + 30% NHS on-costs	£35,640
Annual salary of band 6 RN based on mid-point of scale + 30% NHS on-costs (as per suggestion of having at least one band 6 nurse per 24h from the RCN guidance).	£43,128
Annual salary of band 3 HCSW based on mid-point of scale + 30% NHS on-costs	£25,138

From those various pieces of data, we are able to calculate a gap between existing funding levels and estimated costs of appropriately staffing paediatric inpatient wards following the coming-into-force of these regulations.

Using a nameless example ward with 21 beds, the calculation would look as follows:

Total RN staffing hours required per 24h	21 beds x 6 nursing hours per patient = **126 hours**
Annual RN staffing hours including one band 6 per 24h	126 x 365 = **45,990 hrs** (37,230hrs band 5 + 8,760hrs band 6)
Annual RN cost using a skill mix of band 5 and band 6 salaries + 30% NHS on-costs + 26.9% uplift as per the Act	Band 5: (37,230hrs/1,950hrs) x £35,640 + 26.9% = £863,490 Band 6: (24 x 365) x £43,128 + 26.9% = £245,861 Total: **£1,109,351**
Annual HCSW costs based on 70:30 skill mix of RN required hours + 30% NHS on-costs + 26.9% uplift as per the Act	Total RN annual required hours 45,990 / 70 * 30 ratio of HCSW = 19,710 annual hours (19,710/1,950hrs) x £25,138 + 26.9% = **£322,437**
Total nurse staffing costs based on 100% occupancy	£1,109,351 + £322,437 + £57,853 (supernumerary band 7) = **£1,489,641**
Total nurse staffing gap based on 100% occupancy	£1,489,641- £884,913 (existing nurse staffing funding) = **£604,728**

Therefore for this particular ward, the gap is calculated as **~£605,000**. This represents the maximum possible gap on the assumption that all beds are occupied 100% of the time.

However, we know that bed occupancy in paediatric inpatient wards fluctuates regularly, and is very rarely as high as 100%.

We therefore also ran the exact same calculation as above using the ward's *average peak bed occupancy.* That is the average occupancy high point for the ward based on the available shift data. For the above ward, the average peak bed occupancy is 17.79, meaning on a typical shift during that period, the highest number of patients at one time was ~18. That shift would therefore require the appropriate number of nursing staff for 18 people. This calculation results in a more modest funding gap of ~**£392,000**, representing an approximate minimum threshold gap.

Using these upper and lower calculations gives us a useful approximate range for this ward. However when extrapolated out across all 16 paediatric inpatient wards in Wales for a global view, this range becomes less useful with a lower calculation gap of ~ **-£380,000** (suggesting there is enough money in the system already to fund the necessary posts) and an upper calculation of ~**£6,832,000** (suggesting there is notable shortfall in funding). This is a range of over £7m, and not especially helpful in estimating the cost of this legislation.

The true cost will almost certainly fall somewhere between the two, and using a formula of normal distribution, we are able to estimate where that is likely to be. In short, the *empirical rule* (also known as the 68–95–99.7 rule) is a statistical rule which plots the percentage of values that lie within bands of standard deviation on a normal distribution graph. It is used often in statistics for forecasting rough estimates of final outcomes and used in health services and delivery units in calculating estimated fluctuating demand and capacity.

In this context that translates into taking the mean peak bed occupancy as a minimum requirement and then adding 2/3 of the difference between that and 100% maximum bed occupancy to produce a staffing complement that would meet demand ~95% of the time.

This calculation gives a more realistic sense of the actual staffing requirements for a ward and is more analogous to the flexible, reactive calculations that would be produced using the triangulated methodology outlined in section 25B of the Act.

Total nurse staffing gap for all 16 paediatric inpatient wards based on average peak bed occupancy	**Total nurse staffing gap for all 16 paediatric inpatient wards based on 100% bed occupancy**	**Total nurse staffing gap for all 16 paediatric inpatient wards based on three-sigma calculation.**
~-£380,000	~£6,832,000	**~£4,428,000**

Utilising the best available data we have (acknowledging the aforementioned caveats) in conjunction with the principles from the RCN guidance on appropriate staffing in this setting, the estimated additional staffing cost to the NHS in Wales of extending the Act's second duty to paediatric inpatient wards would be approximately ~**£4,428,000.** As with the equivalent costing exercise from the Nurse Staffing Levels (Wales) Act 2016's RIA, it is acknowledged that this is a rough estimate. However, given the more ward-specific data in place of broader averages, it is likely to be a significantly more accurate methodology than used previously for the adult acute medical and surgical wards.

This estimation is the *additional* cost to health boards in appropriately staffing their paediatric inpatient wards for the initial 12 month period, and would then become part of recurrent spend in subsequent financial years. However, the actual costs would be constantly changeable based on biannual calculations and any significant changes in ward structure or capacity.

It is worth noting that this cost is not shared evenly throughout the six health boards in Wales that service the 16 wards. There is significant variation, ranging from one health board's gap calculated as ~ £20,000 (indicating that they likely have roughly enough funding in the system already) up to another with a gap of ~£1,750,000.

Paragraph 11 of the statutory guidance stipulates that maintenance of the nurse staffing levels will be "*funded from the LHB's (or Trust's) revenue allocation*". Given the relatively small sums of money at play within these estimations, it is not envisaged at this point that additional funding would be provided to health boards following the coming-into-force of these regulations.

You will find a comprehensive view of the full data-sets for each ward and detailed calculations which have been briefly summarised above attached at **Annex 1.**

Monitoring, reporting and administrative costs

There are several administrative processes involved in complying with the second duty of the Act:

- the triangulated calculation process for each ward undertaken twice a year or every time the purpose of the ward changes;
- monitoring the maintenance of the calculated staffing levels;
- producing two board papers a year informing the Board of the results of the biannual calculation and an annual report;
- producing a report to Welsh Ministers every three years which is largely an amalgamation of the three annual reports.

The processes of calculating and maintaining nurse staffing levels are not significantly more labour-intensive than current management of nurse staffing on paediatric inpatient wards, therefore there would be **no estimated additional administrative costs** in that respect.

Despite concerns raised in the consultation process, the original RIA at stage 2 of the Bill fundamentally underestimated the ICT infrastructure that would be necessary for capturing and analysing all the data points necessary to articulate the extent to which nurse staffing levels have been maintained, and the impact not maintaining them has had on patients (as required by section 25E of the Act). In the first three year reporting period under the Act, health boards have grappled with the lack of a single, All-Wales ICT solution to enable this process and allow them to produce comparative reports as required. This has been especially onerous and has consumed innumerable hours of senior nurse time. Thankfully, NWSSP has been overseeing an All-Wales contract for a single e-rostering product, and a ward management module that is being specifically modified to provide health boards with exactly the solution required to allow continuous data capture around patient acuity and nurse staffing levels, and click-button reporting. It had been hoped that this software would be in place within all health boards by the time these regulations come into force on paediatric inpatient wards in October 2021, however due to the interruption of the Covid19 pandemic, this may in fact be delayed to early 2022. Once available, the software will create less of an administrative burden on nursing staff than current practice and likely produce a net cost saving.

As the purchase of the e-rostering software is taking place irrespective of extending the scope of the section 25B duty to paediatric inpatient wards, there is **no additional estimated cost** to the NHS due to these regulations in that respect.

Welsh Government costs

Section 25D of the 2016 Act (as inserted into the 2006 Act) places a duty on Welsh Ministers to issue guidance about the duties under sections 25B and C, and how local health boards and NHS trusts are to comply with those requirements. The original statutory guidance document published in October 2017 has been revised to include reference to paediatric inpatient wards and

undergone a 13 week public consultation process. Further minor revisions will be made informed by those consultation responses.

This work is being undertaken as part of the day-to-day duties of a permanent member of staff in the Chief Nursing Officer's team, and therefore **does not represent an additional cost** to the Welsh Government.

Cost implications for the different options

As it would not seek to change current practice of nurse staffing levels calculation, Option 1 would not result in any additional costs.

In theory, the estimated costs set out above would be the same for both Option 2 and Option 3. The same triangulated method of calculating the appropriate nurse staffing levels would be used in both, so the same estimated gap calculations would be applicable.

The difference between the two would be the statutory obligation for health boards and NHS trusts to actually make the funding available for those calculated nurse staffing levels. The importance of this obligation was highlighted during the first year of implementation of the Act in 2018-19.

One health board's first calculations presented to their Executive Board in April 2018 concluded an additional £4.5m was required to maintain the nurse staffing levels that had been calculated on their adult acute medical and surgical wards. However, it became apparent in November 2018 that the Executive Board had not released that funding, despite the Act leaving no doubt about the obligation to do so. When the Chief Nursing Officer highlighted this statutory obligation, the funding was promptly made available for the additional nurse staffing.

The inherent risk of Option 2 is that health boards would not prioritise the release of that funding in the face of other cost pressures, and that maintenance of the calculated nurse staffing levels would be incomplete, inconsistent across different health boards and incredibly difficult to compare in a meaningful way.

Paragraph 11 of the statutory guidance stipulates that maintenance of the nurse staffing levels will be "*funded from the LHB's (or Trust's) revenue allocation*". Therefore, Option 3 would place the same statutory obligation as illustrated in the above example for Executive Boards to ensure the required funding is available to maintain the calculated nurse staffing levels on paediatric inpatient wards.

Benefits

Given that these regulation merely seek to extend the existing second duty of the Act to paediatric inpatient wards, and that those wards are analogous care settings to adult inpatient wards, the assumed benefits that would be achieved by this legislation would be the same as those asserted when the 2016 Act was passed for adult acute medical and surgical wards.

There has been a recent history of austerity-driven spending constraints in Europe which has had an inevitable impact on the health system and the operating of hospitals, despite concerns from professional bodies about the adverse outcomes for quality and safety of health care. Health system strategies are slowly shifting resources to provide more care in community settings while shortening hospital length of stay and reducing inpatient beds, resulting in increased care intensity for inpatients. Cost containment in hospitals results in higher intensity of services delivered in less time and more rapid patient throughput from admission to discharge. It is argued by the RCN that these changes require more nurses per patient, not fewer, to prevent deterioration in care quality and safety that can harm patients and lead to higher costs if expensive complications such as infections result.

There has been a growing consensus in recent years - supported by several systematic reviews - that the number of nurses available for patient care directly impacts patient outcomes in inpatient wards. More specifically, that *more* nurses equates to *improved* patient outcomes. As well as established legislation in California and the State of Victoria in Australia, this is reflected by guidance produced by NICE and the Royal College of Nursing and the Chief Nursing Officer recommending the implementation of appropriate staffing levels in such wards.

In California, United States of America, fixed ratios were set in 1999 (e.g. 1:5 on medical and surgical wards). To date, fifteen states in the US have legislation aimed at addressing safe nurse staffing but California is the only state to have specific ratios applying to each speciality in all hospitals. Evidence of reported impact in California includes:

- No evidence that ratios have increased costs.[7]
- Hospital nurses typically care for one patient fewer than nurses in other states, the lower caseload is significantly related to lower patient mortality.[8]

In Victoria, Australia minimum nurse to patient ratios were legally mandated in the public sector in 2001 (1:4, plus one in charge on medical/surgical wards). In 2004 the way in which the registered nurse-to-patient ratio was expressed was changed to 5:20, to give more flexibility on registered nurse deployment across the ward. [9] The Australian Nursing Federation (ANF) reports that ratios have led to:

- Better recruitment and retention of nurses and greater workforce stability.
- Adequate numbers of nurses rostered six weeks in advance.
- Directors of Nursing having fully funded budgets to provide safe staffing levels, and a reduced reliance on agency staff.
- Better patient care; beds are not kept open unless there are sufficient staffing levels.
- More manageable nursing workloads.
- Increased job satisfaction for nurses, more workplace stability, and reduced stress.[10]

In terms of the UK and Welsh context, appropriately calculated nurse staffing levels have the potential to significantly reduce costs to the NHS in the long term. At this stage, the information needed to make a quantified estimate of the potential cost-savings is not available. The main benefits are listed below:

- Reduced risk of healthcare acquired infections: the cost to the NHS of surgical site infections is estimated to be around £700 million a year.
- Potential reduction in mortality rates.
- Improved patient experience: potential reduction in adverse events and associated costs.
- Reduced risk of litigation claims due to poor care: the average cost of a claim classed by the NHSLA under the 'nursing' category was £75,000 plus the claim excess and legal advice costs. Dr Goodall, Director General, Health and Social Services, Welsh Government stated the impact within any individual financial year within the Welsh risk pool is around £70 million a year.
- Potential reduced incidence of IV fluid-associated complications by better management of fluids: patients with complications appeared to spend an additional 2.5 days in hospital compared with patients without complications.[11]
- Reduced levels of falls, with a saving of approximately £1,400 per fall avoided.
- Potential reduction in bed days due to providing more effective care, with the associated potential release of resources as a result of a reduced hospital length of stay estimated at £236 per bed day (national tariff, 2014-15).
- Reduction in readmissions within 30 days.

It has also been shown that inadequate staffing levels can lead to a reliance on overtime and temporary (agency and bank) staffing, which can be costly and inefficient. Patients – especially children and young people - demonstrably benefit from continuity of care, but with wards relying upon agency staff for the delivery of care out of necessity, there is an implied increased risk to patients of having members of staff unfamiliar with local processes and procedures, as well as impacting upon the patient experience of care[12].

The 2016 Act's accompanying statutory guidance states that planned rosters "*…should be met with permanent staff, however temporary workers can be deployed if required."* Naturally, bank and agency spend is not going to be eradicated in the short term, and it plays an important role in maintaining nurse staffing levels in certain instances. However the statutory instruction should result in a long term trend away from over-reliance on temporary staff.

A 2011 study[13] found that hospital wards with temporary staff had poorer staffing levels, higher workloads, more sickness absence and lower ward quality scores than wards that were staffed by permanent nurses only. The Keogh mortality review[14] in 2013 found an over-reliance on temporary nursing staff in the hospital trusts it reviewed, noting that there were often restrictions in place on the clinical tasks that temporary staff could undertake.

The *Perfectly Resourced Ward* pilot in Aneurin Bevan in 2012[15], whilst a small study, showed a reduction of 64% in bank and agency staffing costs over the pilot period, compared to the previous six months.

In terms of mortality, a study of nurse staffing and education and the impact on hospital mortality in nine European countries concluded that: an increase in a nurses' workload by one patient increased the likelihood of an inpatient dying within 30 days of admission by 7% (odds ratio 1·068, 95% CI 1·031—1·106), and every 10% increase in bachelor's degree nurses was associated with a decrease in this likelihood by 7% (0·929, 0·886—0·973). These associations imply that patients in hospitals in which 60% of nurses had bachelor's degrees and nurses cared for an average of six patients would have almost 30% lower mortality than patients in hospitals in which only 30% of nurses had bachelors' degrees and nurses cared for an average of eight patients.[16]

Benefit implications for the different options.

As with the estimated costs, as it would not change current practice, none of the above-identified potential benefits would be achieved directly by selecting Option 1.

Similarly, as with the costs, the above-mentioned assumed benefits would be applicable to both Option 2 and Option 3.

The difference would be the probability of those benefits being realised and to what degree.

As Option 3 mandates a consistent approach in Wales, bound by a statutory obligation, the scale of the benefits would be more uniform nationally, and easier to measure, compare and draw causal associations. Further, this option would ensure the highest possible probability of achieving those assumed benefits in the long term.

Conversely, without that statutory obligation dictating practice, Option 2 is shrouded in uncertainty. The extent to which the calculated nurse staffing levels are funded and maintained would be entirely unpredictable, almost certainly inconsistent between different health board areas, and likely prone to regular fluctuation even within the same health board based on periodic finance trends.

As the assumed benefits outlined above are long term aims, they are more likely to be realised following long periods of consistent practice and gradual cultural change in organisations. That kind of long term *critical mass* cultural change would be far less likely under Option 2 where there are near infinite potential scenarios of varying organisational practice, and shifting levels of inconsistency over time.

Risks

Option 1

The main risk of maintaining the status quo is that the potential assumed benefits of options 2 and 3 (as outlined above) would remain unachieved.

Option 2

The risk outlined above would also be applicable to this option.

Variability

Firstly, as touched upon above, adherence to the various duties set out by the Act without the weight of the statutory obligation would be massively variable. This includes the extent to which:

- the triangulated methodology would be used to calculate appropriate nurse staffing levels and how frequently this is undertaken;
- all reasonable steps are taken to maintain those calculated nurse staffing levels;
- funding is released by the health board for the calculated additional staff needs;
- patients and the public are kept informed of the calculated nurse staffing levels.

The scope for inconsistency and variation multiplied across the six health boards that service paediatric inpatient wards means that the likely effects of Option 2 are entirely unpredictable. The potential costs and benefits could range from: none whatsoever if the non-statutory guidance was not adhered to at all; to exactly the same as Option 3 if the guidance were adhered to as consistently as if it were statutory.

Health outcome inequalities

This likely variation in practice would risk exasperating health outcome inequalities in Wales. It would be reasonable to assume that health boards facing acute financial strain would be most likely to refuse to fund the nurse staffing levels calculated by their senior nurses. That could mean children and young people in Wales could be receiving demonstrably different quality of care based on geography.

Further, the scope for variable practice when applying the triangulated calculation process at ward level (if not led by statutory guidance) could reasonably lead to different quality of care even within a single health board.

Option 3

The risks linked to variability of application outlined above would be almost entirely reduced by the statutory obligation of Option 3. Based on experiences

of the first three years of implementation of the 2016 Act in adult settings, some minor local variation is inevitable. However the degree of variation is negligible due to the national standards and templates coordinated by the All Wales Nurse Staffing Group (which consists of membership from all health boards), the authority of which is entirely underpinned by statutory requirements.

As already referred to on page 12, the most egregious example of local variation during that period was a health board's refusal at executive level to fund the calculated nurse staffing levels. The authority of the statutory requirement is what remedied this variation almost immediately.

A risk posed by Option 3 mirrors one of the main risks to passing the Act in 2016. That is an inadequate number of qualified registered paediatric nurses within Wales to maintain the nurse staffing levels that would be calculated.

The issue of registered nurse staffing shortage is well publicised, and affects every healthcare service in the developed world. The 2016 Act was not seen as an immediate solution to that issue, but it is conceivable that in the long term, the greater authority of nurses' professional judgement in determining appropriate staffing levels, and the more detailed reporting of nurse staffing data underpinned by the duties of the 2016 Act would be a driver for greater commissioning of registered nurses.

Whether a direct result of the 2016 Act or not, commissioning of adult RN training places has risen steadily and significantly from 876 places in 2016 to 1,210 in 2020. Similarly, commissioning of child RN training places has risen from 100 places in 2016 to 154 in 2020[17]. Additional targeted commissioning of paediatric nurses alongside the passing of these regulations would further mitigate this risk.

There is also flexibility within the 2016 Act itself to help mitigate this risk in the short term. Health boards and trusts are required to take "all reasonable steps" to maintain their nurse staffing levels. This could include utilising bank/agency staff and reducing bed capacity of wards where considered necessary for that purpose, as listed in the 2016 Act's statutory guidance.

Options conclusion

Given the unpredictable likelihood of variation in application, and the resulting possible health outcome inequalities resulting from Options 1 and 2. Option 3 is strongly recommended as preferable.

8. Consultation

As per section 5 in Part I of this explanatory memorandum, there was no statutory obligation to consult on these regulations themselves as the 2016 Act (which underwent multiple public consultations) grants Ministers the power to use them for this purpose without prior consultation.

As also explained above, the proposed extension of the section 25B duty to paediatric inpatient wards, and consequential necessary amendments to the

statutory guidance, were the subject of [significant] stakeholder engagement. Further, a 13 week public consultation[3] was undertaken on the revised statutory guidance as required by section 25D(4) and as summarised in Part I.

9. Competition Assessment

Not applicable.

10. Post implementation review

Under section 25E of the Act, health boards and NHS trusts have a duty to report to Welsh Ministers every three years on the extent to which nurse staffing levels have been maintained on the wards to which these duties apply, the impact those organisations consider that *not* maintaining those levels has had on care, and any actions taken in response to not maintaining nurse staffing levels.

Following the extension of this section to paediatric inpatient areas, this duty to report would also be applied to those wards. Health boards will be submitting their first such reports under 25E in May 2021.

It was originally intended that these regulations would come into force in April 2021, however the Covid19 pandemic in 2020 disrupted health board preparations for the extension to the extent that the Chief Nursing Officer deemed that date to be an unreasonable expectation. The coming into force date was therefore delayed by six months to 1 October 2021.

The 2016 Act defines the *reporting period* under section 25E as 3 years from the commencement of section 25B. This means that the reporting period for paediatric inpatient wards will not begin with the coming-into-force date of the regulations, but will be synchronised with that of adult medical and surgical wards.

In practice this would mean that the first reports on paediatric inpatient wards would be submitted to the Welsh Ministers in May 2024 at the same time as the second three year report for adult inpatient wards despite containing only two and a half years' worth of data.

As well as these tri-annual statutory reports, health boards and NHS trusts submit an annual report to their boards based on the same requirements. They then amalgamate those to form the three year report. These annual reports are monitored by the office of the Chief Nursing Officer in partnership with the All Wales Nurse Staffing programme to ensure a more regular periodic review of the Act's implementation on the ground.

There is an intention to commission an independent review of the implementation and costs/benefits impact of the Nurse Staffing Levels (Wales) Act 2016, however the Covid19 pandemic has delayed the development and

commissioning of a brief. This will be revisited and pursued in due course following the end of the first three-year reporting period in April 2021.

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