DÁIL ÉIREANN

ROGHCHOISTE UM SHLÁINTE

SELECT COMMITTEE ON HEALTH

Déardaoin, 10 Márta 2022

Thursday, 10 March 2022

Tháinig an Romhchoiste le chéile ag 9.30 a.m.

The Select Committee met at 9.30 a.m.

Comhaltaí a bhí i láthair/Members present:

Teachtaí Dála/Deputies	
Colm Burke,	
David Cullinane,	
Stephen Donnelly (*Minister for Health*),	
Bernard J. Durkan,	
Róisín Shortall.	

Teachta/Deputy Seán Crowe sa Chathaoir/in the Chair.

Patient Safety (Notifiable Patient Safety Incidents) Bill 2019: Committee Stage

Chairman: Apologies have been received from Deputy Cathal Crowe. Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise, or make charges against a person outside the Houses of the Oireachtas or an official either by name or in such a way as to make him or her identifiable. I remind members that they are only allowed to participate in this meeting if they are physically located in the Leinster House complex. In this regard, I ask all members, prior to making their contribution to the meeting, to confirm they are on the grounds of the Leinster House campus.

This meeting has been convened to consider the Patient Safety (Notifiable Safety Incidents) Bill 2019. I welcome the Minister for Health, Deputy Donnelly, to the meeting.

Minister for Health (Deputy Stephen Donnelly): I thank committee members for the opportunity to present the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 on Committee Stage. The Bill is extremely important and it will change the culture in our health services in a very positive way. I acknowledge the broad support the Bill received on First and Second Stages.

When things go wrong, patients and their families expect at least three things. They expect to be told honestly what has happened, what can be done to deal with any harm that has been caused and what will be done to prevent a recurrence of such harm to anybody else.

In every health service the world over things will, of course, occasionally go wrong, and what matters when they do go wrong, when mistakes and errors occur, is how the health service responds and deals with these situations. Much has been done to advance open disclosure in our health service. The HSE introduced a national open disclosure policy in 2013, and there are many examples of open disclosure occurring as it should in our health service. Unfortunately, it does not always happen. All of us here today are aware of these tragic cases. This Bill provides for mandatory open disclosure of serious patient safety incidents. It provides for the notification of those reportable incidents to the relevant regulator and extends the remit of HIQA to private hospitals. It also contains provisions supporting clinical audit in the health service. This Bill will lead to a safer, better health service by placing patients and their needs front and centre.

As my colleagues are aware, the Government approved this Bill in December 2019, subject to certain amendments, and it passed First and Second Stages in the Dáil on 12 December 2019. It was due to proceed to Committee Stage in early 2020 but events overtook us with the arrival of Covid-19. I would like to outline a number of amendments, some of which were part of the Government decision when the Bill was approved in December 2019. I will first seek to clarify the amendment to section 9 of the Health Act 2007, which will strengthen the ministerial powers to request an investigation by HIQA into ongoing patient safety risk in Ireland's health and social services.

I am also proposing an amendment to section 12 of the Bill, which addresses openness and transparency. As previously drafted, section 12 set out that both health service providers and health practitioners, when making an open disclosure under this Bill, must provide all relevant information to the patient or their relevant person. Where appropriate, they must also inform other health services of a notifiable incident. I have now added further draft provisions to section 12 that expand the impact of this section and ensure these provisions are enshrined in the relevant policies set by the HSE and national standards set by HIQA. It also ensures they are

enshrined in the codes of professional conduct or practice set by the relevant regulatory authorities.

Schedule 2 to the Bill contains a list of amendments to the Civil Liability (Amendment) Act 2017. These amendments are purely technical. They aim to align the two pieces of legislation with specific reference to the organisation of the open disclosure meeting, the provision of information to the patient and their family, and the procedure to follow should a patient not wish to participate in an open disclosure meeting. These amendments do not introduce any new substantive provisions to either Bill.

These three amendments are given effect in a number of sections throughout the Bill and I will outline the detail of the amendments as they arise.

I wish to flag two amendments I will be introducing on Report Stage. First, I propose to give the HIQA chief inspector of social services a discretionary power to carry out a review of certain serious patient safety incidents that occur during the provision of healthcare where some or all of the care of the patient is carried out in a nursing home. This proposed amendment will seek to support patients and their families when something goes wrong with the clinical care they received in a nursing home. It will ensure appropriate external processes are in place to review serious patient safety incidents. The amendment follows the report of the Covid-19 nursing home expert panel recommendations that call for suitable structures to be put in place for external oversight of individual care concerns arising in nursing homes. This power will not replace the responsibility of nursing homes to address concerns that are raised by patients and families. It will put in place an appropriate escalation pathway to ensure these concerns are addressed in a way that will provide answers to families and patients.

Second, the overarching intention of the Bill is to embed and support a culture of open disclosure. It is fair to say that many aspects of the Bill have been informed by the learnings from CervicalCheck, particularly the need to ensure accountability by service providers and clinicians in carrying out open disclosure to patients and families. I, together with my Department and the national screening services, have given a significant amount of consideration to these learnings and the work of the expert reference group on interval cancers. These expert reports were commissioned as part of the Scally review in 2018. They set out a new and comprehensive approach to reviews of interval cancers in people who have been screened by the breast, bowel and cervical cancer screening programmes. I intend to introduce a notifiable incident directly relating to cancer screening services. These measures are currently with the Office of the Parliamentary Counsel for drafting. I will introduce this amendment on Report Stage.

Chairman: I remind members that if a vote is called, they must physically come to the committee room to vote. There are 54 amendments tabled, five of which have been ruled out of order. I ask members to work with me to get through the Bill as quickly as possible.

Section 1 agreed to.

SECTION 2

Chairman: Amendments Nos. 1, 7 to 9, inclusive, 12 to 14, inclusive, 17 and 19 are related and may be discussed together.

Deputy Stephen Donnelly: I move amendment No. 1:

In page 8, line 3, to delete "shall be construed in accordance with *section 17*" and sub-

stitute the following:

"means holding such meeting or such clarification by means of the telephone or the internet (or other similar method of communication)".

The amendments in this grouping are technical amendments that clarify the method by which communication to families can take place during open disclosure. For example, amendment No. 1 clarifies how a meeting can take place other than in person. Certain of the amendments remove the phrase "in writing" from several points of the Bill as it is redundant in the drafting. They are minor technical amendments and have no material impact on the provision of the Bill.

Amendment agreed to.

Section 2, as amended, agreed to.

SECTION 3

Deputy Stephen Donnelly: I move amendment No. 2:

In page 9, line 28, to delete "professional" and substitute "practitioner".

The amendment seeks to replace the word "professional". It is a technical amendment to replace the word "professional" in line 28 with the correct phrase, which is "practitioner".

Amendment agreed to.

Section 3, as amended, agreed to.

NEW SECTION

Chairman: Amendments Nos. 3 and 49 are related and may be discussed together.

Deputy David Cullinane: I move amendment No. 3:

In page 10, after line 39, to insert the following:

"Patient Safety Council

4. (1) The Minister shall, within 6 months of the passage of this Act, establish for the purposes of this section, a Patient Safety Council, subject to *subsection (5)*.

(2) The Patient Safety Council, so established by the Minister pursuant to this Act, shall meet annually, within the first 3 months of each year, on however many occasions as it deems necessary to complete a report mandated in *subsection (3)*.

(3) The Patient Safety Council shall furnish to the Minister a report, subject to *subsection (4)*, within the first 3 months of each year.

(4) The Annual Report of the Patient Safety Council shall review the operation of this Act in the prior year and shall include:

(a) the views of stakeholders referred to in this Act and others as the Patient Safety Council may decide relevant to the responsibilities of the Patient Safety Council;

(b) the number and nature of incidents notified under this Act in the prior year;

(c) recommendations for amendments to this Act and any other Act as may be deemed relevant by the Patient Safety Council;

(d) recommendations for addition to *Schedule 1* of this Act;

(e) any other details which the Patient Safety Council may deem pertinent;

(f) in its first report, recommendations for ensuring that where harm has occurred and has been admitted, that some form of redress or scheme for redress is established under the Act for the avoidance of litigation, to review in particular the appropriateness of sections relating to admissions and liability.

(5) Membership of the Patient Safety Council shall be on appointment by the Minister and shall include:

(a) 2 patient advocates at minimum;

(b) a representative of the Authority;

(c) a representative of the Commission;

(d) a representative of the Medical Council;

(e) a representative of the Nursing and Midwifery Board;

(f) a representative of any other professional regulatory body or any other body as the Patient Safety Council may deem relevant and recommend to the Minister from time to time.".

I welcome the Minister. I certainly will be supporting the speedy passage of the Bill through the Oireachtas. All present know its importance. There are many related issues with which we also need to deal, including safeguarding legislation, which I hope the Minister will be in a position to bring forward this year. There are issues relating to the rights of social care teams and safeguarding teams to investigate allegations of abuse and neglect. There are issues of accountability at management level when there are failures. Such failures have been highlighted time and again. All of these issues are related to what we are trying to achieve in the Bill. I welcome this element of it. Mandatory reporting is important. I wish to put on record that my thoughts are with Vicky Phelan, Róisín Molloy and many other men and women who were victims of a lack of mandatory reporting and mandatory disclosure. In my view, we are here today to improve systems for them.

The Minister made a point in his opening statement that is relevant to the amendment I am proposing to the Bill. He stated the Bill should ensure safer and better health services for patients. Of course, I hope that is what the Bill will do. Any improvement in that direction is welcome. The patients, however, will be the judges of whether it does what it needs to do, whether the Bill, once implemented and operational, will make health services safer and more fit for purpose and, as the Minister stated, engender a new culture of reporting within the health service. All present hope that is what will happen.

The amendment seeks to establish a patient council. The reason for that is obvious. Patient advocates and patients themselves should have a voice in respect of the supervision of the Bill when enacted. It calls for, at minimum, a report to be published each year by the patient council. Obviously, it will meet as often as it deems necessary to review the operation of the legisla-

tion, but also to make recommendations. As the Minister stated on Second Stage, the notifiable incidents under Schedule 1 may well be changed. The Minister has the power to do so as time progresses. If there are other incidents that need to be included in that Schedule, that can be done. Surely, however, patients should have a voice in that process as well.

I tabled the amendment in good faith. I know many patient advocates and patients who have been through a very difficult time. It pains me to say it but there is a significant amount of distrust in the system simply because many people quite rightly believe there is not just a lack of a culture of open disclosure but also a lack of a culture of accountability within the health services at a senior management level. I am not pointing a finger at any individual; it is a culture issue. One just has to look at all the scandals there have been. I will not go through them all. We know the full range of scandals involving patients being let down and becoming victims of a failed process. Establishing this council would be a very important message to send in the context of giving them a sense that they will be part of this process and journey.

I will leave it there. In the spirit of getting through all the amendments, it is important that I do not labour the point. I have made the argument for the amendment and I ask the Minister to consider accepting it.

Deputy Stephen Donnelly: I thank the Deputy. I agree with the intention of the amendment and everything he has just said. I will not be accepting the amendment because there is an independent patient safety council in existence. The council provides advice and guidance to the Minister for Health on a broad range of perspectives on the development of patient safety policy. It was appointed by the then Minister in 2019 and held its first meeting on 27 February 2020. By engaging a broad range of perspectives in patient safety policy, including those of the patient and the service in question, the work of the council leads to enhanced policymaking. The council members bring a wide variety of expertise and experience, which is important, including citizens, education, patient safety, health policy, healthcare leadership and more. The council is chaired by Ms Noeline Blackwell who we are all very aware of. She is a person of excellent standing and CEO of the Dublin Rape Crisis Centre. To the Deputy's point, the council obviously needs to meet and does so two to three times a year. It also agrees on an annual work programme. As part of the 2020 programme, the council was asked by the then Minister to carry out some work in the area of open disclosure. Last year, it provided me with recommendations on a national policy framework for open disclosure in healthcare in Ireland. I would be very happy to share that report with the committee. I will check if it has been published, but I certainly see no reason why we should not provide it. This framework is very much to assist organisations and clinicians to apply the principles of open disclosure and to communicate with patients where healthcare does not go to plan. The framework is now being drafted and it will sit along this legislation to give guidance to healthcare organisations.

In short, I agree with the Deputy's points. We have quite a robust council in place under an excellent chair that is already looking at open disclosure. I propose, because I agree with everything the Deputy said, that the committee or I could write to the Independent Patient Safety Council and ask it in whatever the appropriate period is, possibly a year after operation, to do a review and report back to the Oireachtas and me with its findings. Would that work?

Deputy David Cullinane: I would accept that. Were the Minister to write directly to the council, it would have more weight. If members agree, this committee could do so as well. If the Minister commits to that, I will withdraw the amendment.

Deputy Stephen Donnelly: I am very happy to commit to that.

Amendment, by leave, withdrawn.

Sections 4 to 6, inclusive, agreed to.

NEW SECTION

Chairman: Amendment No. 4 is ruled out of order as it involves a potential charge on the Exchequer.

Deputy David Cullinane: Can I speak to the section when we get to that point?

Chairman: The Deputy can speak to the section now.

Deputy David Cullinane: I will not talk the Minister through the amendment as it is has been ruled out of order, unfortunately. I do not see why. I cannot see how the amendment would have incurred a cost to the Exchequer to the point that it was ruled out of order but that is not for the Minister and I to have a discussion on.

I will speak very briefly to this point in the section and on what I was seeking to do, which is that any individual who is employed by the health services should be mandated to report incidents under Schedule 1. If it is left to only some clinicians and not others, the difficulty is some of them may not report. There are robust procedures and processes for failure to report but it is possible some incidents may not be captured in instances and situations where others working in or around an individual who is mandated to report are also aware of a notifiable incident, which should be reported by that individual. It is very important we get this right and that any individual who has a sense that something is wrong and works in the healthcare service should be mandated to come forward.

I have spoken to a number of advocate groups on this matter and we do not want a situation where there is over-reporting. I appreciate there is a balance to be struck but, at the same time, we can put safeguards in place to protect the rights of healthcare staff who may well come forward, which is why the amendment allows for people to report an incident to HIQA, for example, as an alternative and added protection. Nobody should have any fear about coming forward in respect of his or her job or standing in the health services. We are doing this because it is about patient safety and it is the right thing to do. Incidents should be reported and followed by fair processes to investigate any notifiable incidents or complaints made under the mandatory reporting process. Anyone in the health service needs to be properly protected when he or she comes forward.

The point I am making is what I was seeking to make in the amendment. As that has been ruled out of order, I can only speak to it in the section, namely, that we should broaden the scope of who should be making reports and who should be mandated to make reports. It should be all those who work in healthcare settings.

Chairman: Is the Deputy speaking to amendment No. 5 as well? It is part of that section.

Deputy David Cullinane: Yes. It is the same point.

Deputy Stephen Donnelly: I will speak to the section and amendment No. 5. We may stray into-----

Deputy David Cullinane: No, sorry. Amendment No. 5 is different. I will come back to that.

Amendment No. 4 not moved.

SECTION 7

Chairman: Does the Deputy wish to speak to amendment No. 5 now?

Deputy David Cullinane: I move amendment No. 5:

In page 12, between lines 33 and 34, to insert the following:

"(2) A health services provider shall make every effort to ensure that the patient and relevant person are informed as to the potential for engaging and sourcing a patient advocate and, where an advocate is chosen by the patient and/or relevant person, the advocate is included throughout the disclosure process as a relevant person.".

This amendment places an obligation on the provider to provide information to a patient in respect of a patient advocate. That is very important because we know how difficult it can be for some family members to work through all of this. For someone who has no experience of advocacy or of how to navigate through what can be the maze of the HSE, the system, reporting systems and so on, the role of a patient advocate, as the Minister knows, is very important. With this amendment we seek to place an obligation on the provider to ensure that it is mandated to provide information to a patient on how to engage the services of a patient advocate, rather than simply leaving it to a patient to have to try to find all of this out, sometimes by having to employ the services of legal representatives and incurring more costs. It is to aid patients in accessing a patient advocate and placing an obligation on the provider to do everything possible to enable that to happen.

Chairman: The Minister can speak to amendment No. 5 and to the section.

Deputy Stephen Donnelly: I also fully agree with the intent of amendment No. 5. The good news is we now have a patient advocacy service that is growing. The Patient Advocacy Service, PAS, was set up to provide exactly what the Deputy is, quite rightly, calling for, which is free and independent advocacy for users in the acute system who intend to make a formal complaint regarding the care they receive. The complaints come through the HSE's Your Service, Your Say process. PAS is also there to help those who have been involved in a patient safety incident, which is obviously the topic of the legislation before us. It was established for public acute hospital users. However, since June of last year, we have extended that to HSE-operated nursing homes as well.

Since its establishment, the service commenced operations nationally. There are hubs in centres with the highest activity, namely, Dublin, Cork, Limerick, the midlands and Galway. The service goes to all locations to meet patients and service users as required. Currently, 20 staff are employed by PAS and recruitment is ongoing. Last year, it received 1,200 new contacts so it is doing an awful lot of work. That is required advocacy arising from more than 3,300 separate complaints. PAS is there, it is very active and it is working around the country.

While I will not accept the amendment, since we already have the service in place, I am happy to commit to asking my officials to engage directly with the HSE to make sure there is a very wide understanding that PAS is there, that it is free and that it is very responsive. I agree entirely that there are many cases where patients need advocates. PAS provides that expert advocacy service.

Section 7 is a very important section. It establishes the obligation of mandatory open disclosure. While amendment No. 4 has been ruled out of order, I will address some of the issues through discussion of the section. The view is that it is very important a clear responsibility and accountability is placed on the service provider and the most relevant senior clinician. That is what this is about. The Deputy referred to protected disclosure. He is correct. Those protections are afforded under different legislation, namely, the Health Act 2004 which was amended in 2007. The protections for people coming forward are very important and real but covered under separate legislation. I looked at what other countries do. We cannot find any other country where there is an obligation on everybody. There is a concern where there could be someone in a hospital ward, for instance, with no clinical training or not the right level of clinical training who might see something that they are not really qualified to know whether it was a serious incident or whether should it have happened. It might be that it is part of normal care or maybe it is not but it could create anxiety for them that they feel legally obliged to report all of these. That is why Ireland and other countries keep it to the organisation. This would introduce an offence with serious penalties. The legislation lays out who the lead person is and there is back-up for the next person if that person is not available. That is how the section is structured. That is the right way to go rather than putting an obligation on everybody.

Deputy Róisín Shortall: I want to raise a couple of points under this section. First, the patient advocacy service is very good but it is under-staffed. I hope the Minister will move quickly to recruit additional staff. The Minister also made the point that it does not work in private nursing homes. Given the extent to which the State depends on private nursing homes and that they are largely funded by State money, is there an intention to extend the remit of the patient advocacy service to private nursing homes?

There is a wider point on the section relating to clinical accountability. Separate to this, there is a recommendation in the context of the regionalisation of the HSE to introduce legally binding clinical accountability where there would be regular reviews. The Minister referred to what happens in other countries. I remember Professor Tom Keane talking about this in relation to his own role in Canada, for example, where at the end of each year there was a kind of performance assessment which he and all other consultants had to undergo. Is it intended work will start on that proposed legislation, which would be part of a piece with this legislation, to ensure it is not only when there are adverse events but that clinical assessment would be carried out on an ongoing basis by the hospital concerned?

Deputy David Cullinane: I want to respond to some of the Minister's points. First on the patient advocacy service, yes, it is a service that is available. As Deputy Shortall rightly said, it is under-resourced. It does not apply to private nursing homes. I accept the Minister's bona fides that he will engage with the patient advocacy service in the context of the passage of this Bill and will look at resourcing and staffing issues, but I will press the amendment. However, I will not call for a vote on any of the amendments because I want the Bill to pass as quickly as possible for the obvious reasons.

Returning to the broader point around the section, the Minister spoke on who would be obliged or mandated to make a report. I accept much of the logic of his response. That is why I said we have to be careful. There has to be a balanced approach. I tabled an amendment and I am pleased the Minister has looked at the matter to see how it operates internationally. However, we must also be honest. I do not want to prejudge reviews, processes and audits which are now in place around CAMHS in Kerry. However, some of the senior officials were before the committee some weeks ago. There was a failure in clinical supervision at the very top. It is ac-

cepted by the HSE. There were failures at management level and at very senior clinician level. I understand that in CAMHS in Cork it was a social worker who made disclosures, not because she was mandated to do it but because she felt it was the right thing to do. I just have a fear here.

While there is some logic in what the Minister said and you do not want to create the anxiety that he spoke about where everybody feels they have to report everything, that is not what the Bill does. Schedule 1 sets out very clearly what is a notifiable incident. Clearly any mandated report has to be under that Schedule by using this Act. We can improve in this area. This goes back to where I sought a separate patient council that would look at the operation of this Bill given its sheer importance that this is something that as part of that review process would be looked at. I hope it is not the case, but I fear that we could end up, after the passage of this Bill, in one, two or three years' time, where we have had a number of incidents where those senior clinicians or relevant senior clinicians the Minister spoke about may not have reported what should have been reported. Then there will be a failure in that area. Yes, there are processes to deal with that but there may be other staff members in and around that clinician who were aware of incidents but were not mandated to report them. We will then ask why not? We will find the reason they were not making the reports is that they were not mandated to do so. If that is the case, then the Act will have to be amended.

I very much hope this Bill will work and that we do not have those kinds of situations but the possibility of those arising is very real. We can look at examples of failures at management and senior clinician level. It very rarely happens. We have excellent staff in our health service. The senior clinicians are really good at what they do and it is very rare that we have these kinds of failures. However, they occur and when they do and there are failures on the part of a senior clinician, there should be responsibility on the others to come forward. My amendment might not have been the best way to do it and maybe there is a happy medium or a balance between what I was proposing and what is in the Bill. For the purpose of moving this debate on, I will leave it at that. I welcome the Minister's response but I fear it is an issue that we may have to return to in the future. I hope that is not the case.

Deputy Stephen Donnelly: Deputy Shortall asked if we will extend the remit of the patient advocacy service. Yes, we will. We want to extend it to nursing homes for all the obvious reasons. A tendering process is now under way. On the need for a bigger service, yes, we are expanding the service with more funding and staff and a wider remit. I fully agree.

There is much overlap in the points made by Deputies Cullinane and Shortall on the really important question of clinical accountability. I will try to decouple them slightly. When I was discussing the Bill with Department officials, we were teasing out some of these points. It was put to me that they are linked. We are trying to strike a very delicate balance between fostering a culture of openness, which is what this Bill is all about - it is all about mandatory open disclosure - and a culture where people are afraid, whether they should or should not be, to disclose because of what might happen to them. The advice we have from looking around the world at systems that do this better than we do is to try to keep them separate insofar as possible. For example, this Bill rightly contains requirements around apologies. However, they cannot be used as part of court cases or admissions of liability. My understanding is that Canada, for example, had a similar system. We are trying to strike a really delicate balance. First, we are telling people that under the 2004 Act they have protections if they want to come forward under protected disclosures. Second, there are clear guidelines in place regarding mandatory open disclosure. Now this Bill adds another serious layer to that. It states it is a legal requirement and it is an offence if one does not do what one is meant to do in terms of mandatory open dis-

closure. At the same time, to refer to the points of both Deputies, which I fully agree with, there has to be accountability. There has to be clinical accountability and there has to be managerial accountability. We can refer to numerous examples, including south Kerry. We are trying to find a very fine line, or trying to walk the right balance, and get this balance right. This Bill is about the mandatory open disclosure part, not the accountability part.

However, we are proceeding with the regional health areas, RHAs, for many reasons. I was in Galway last week looking at the emergency departments and various other services. The case for the regional health areas from a patient service perspective is clear as day. We have many patients with delayed transfer of care and delayed discharge. Patients in emergency departments need those beds, yet there are separate organisations running the hospitals and running the community side of things. Obviously, it should all be the one organisation. The RHAs are very important from a continuity of patient care perspective. It is also through the RHAs that we will put the systems of accountability in place at the clinical level and at the managerial level. That work is ongoing. Not only is the work ongoing, I have also appointed an advisory group to me on the implementation of that. This is one of the areas on which that group will be providing feedback to me, to make sure that we get the right balance and that we have accountability, which we must have, but it does not come at the cost of creating a culture where people are afraid to step forward and admit when things have gone wrong.

Deputy Bernard J. Durkan: We are committed to open disclosure, but we still do not have open disclosure. That is the contradiction that has to be addressed. There has to be a system whereby the person is encouraged to come forward and that everybody else agrees as well. If a decision is made and people think they will all be in trouble if it is disclosed, to my mind the answer is that they will all be in trouble if it is not disclosed. We have to find the right level at which to intervene and the right level of incentives to ensure that the purpose of the Bill is served. The culture is not going to change overnight and we could be here six months hence, a year hence and five years hence. The Bill is as good as it operates and works and identifies the issues as they come along and are dealt with. Some issues have been dealt with in various institutions over the past six months, but some issues have spectacularly not been dealt with. I believe we have to get an equilibrium as soon as possible.

Deputy David Cullinane: I wish to make another point, because this is an important discussion on accountability and we probably will not get a chance to discuss those issues again in this Bill. I realise we are talking about accountability in respect of mandatory open disclosure, but I will outline my experience of the HSE. When the Minister was in the Opposition and on this committee, he had to deal with a lot of scandals and crises in health. Many people who have come before this committee have had to testify to failures at management level, clinical governance management, standards, quality care and so forth. There is a sense that nobody is held to account at management level. We have reviews and processes, but at the end of it people do not see that there has been accountability at senior management level. Obviously, we will have separate conversations on the wider areas in that regard when the Minister comes forward with his plans for regional health areas. We have all sorts of concerns in that regard as well, to which we will return. Everybody on the committee wants that to be right. However, to get accountability right, there must be accountability at senior level at the core of an organisation. If there are very senior clinical failures, nobody is ever held to account that I can see. I will not attempt to talk the Minister through all the incidents. I referenced some of the most recent ones but we could go back over many years.

Can the Minister talk through - people will want to hear this to better understand from the

Minister's perspective how this is going to work - what the sanction is if a senior relevant clinician does not report something that the authorities then deem should have been reported and there was an obligation on the clinician to report it? Separate from that, the Minister might take the opportunity to talk about his view on accountability at management level. When I deal with organisations such as the Irish Association of Social Workers, Safeguarding Ireland and others, the one issue they continually come back to is that if one does not deal with cultural problems where there is a lack of accountability at senior level in the HSE, we will have these incidents happening repeatedly. I know that it is a tricky area and I appreciate it is not an easy area to resolve, but it is one we have to start addressing. We can start to do it in this Bill, certainly when it relates to mandatory open disclosure. Can the Minister outline exactly what the sanctions would be for somebody who fails to report and who should have reported?

Deputy Stephen Donnelly: We are in agreement about the need for formal structures and the culture as well. In this Bill there is clear accountability for not disclosing. That is the purpose of the Bill. If somebody is deemed to have not complied with the mandatory open disclosure requirements for the serious patient events as laid out in the Bill, which can be added to by regulation, the person will have committed an offence. We are jumping ahead as it is section 49, but if the Chairman wishes, I am happy to speak to that now.

Chairman: I would prefer if you did not. I prefer to concentrate on it section by section.

Deputy David Cullinane: I can wait until then.

Chairman: The Minister can outline what is in the Bill if he wishes.

Deputy Stephen Donnelly: Section 49 address the offences and the penalties. A health service provider which fails to comply with the obligations to make an open disclosure of a notifiable patient safety incident without reasonable excuse shall be liable on summary conviction to a class A fine. A health service provider that fails to comply with the obligation to report a notifiable patient safety incident externally to the appropriate body will be liable on summary conviction to a class A fine. A summary offence is one which can only be dealt with by a judge sitting without a jury, that is, in the District Court. Under the Fines Act 2010, since January 2011 there are five categories or classes of maximum fine applying to summary convictions. If somebody is liable on summary conviction to a class A fine, the fine is up to a maximum of €5,000. The health service provider must in its defence make all reasonable efforts to ensure compliance with the relevant provisions.

Chairman: I did not want to open this up again, but I call Deputy Shortall.

Deputy Róisín Shortall: This is probably the most important element of the legislation. Deputy Cullinane referred earlier to our experience in this committee with the south Kerry CAMHS issue. At that meeting, we were trying to get to the point where we could identify who was in charge and who was responsible. It was impossible to do that because there was no clear chain of command at all. There were various different management bodies. There was the administrative one within the CHO, but then each of the different disciplines have their own management structure and they report up through that, whether it is physiotherapy, public health nurses or whatever. The RHAs will assist in devolving power and responsibility down through the service. The existing management structure is completely dysfunctional even within each of the CHOs. The Minister made the point about having a single budget and that it makes sense as it means we do not have delayed discharges because there is no money for home care. All of that is very important but equally important is having a clear chain of command and

a management structure so that when something does go wrong, the buck stops with identifiable people. When the Minister quotes section 49, he refers to how a health service provider that may have committed an offence can end up being fined and so on but what is a health service provider? The HSE is a health service provider but there is no point in fining the HSE. It must be tied into legal accountability for named posts within the management structure. This is what concerns me. I have made this point a few times when problems have arisen within the HSE. You get the sense that everybody is responsible and yet nobody is responsible. I think the term "health service provider" is a very wide and ambiguous one. It does not fill me with confidence that there will be a way of identifying whether that the buck stops with "X" be that at a clinical or administrative level. This is what we need to do. If people are employed on very high salaries, responsibility must come with that. This is the only way. There must be consequences for individuals concerned when the job is not done properly or responsibly. The fact that it is still quite loose concerns me.

Deputy Stephen Donnelly: The definition of a "health service provider" is detailed in section 3. It could be an individual hospital, for example. While I understand the points being made, I think they are probably beyond the scope of this legislation. This legislation is around trying to instil in law an obligation for mandatory open disclosure. It is one that will be taken very seriously by the healthcare providers and clinicians. What it is doing is backing up. It is another layer of defence because the HSE mandatory disclosure guidelines are already in place and are taken seriously.

There is a broader conversation into which we have very understandably moved around accountability generally. As I said earlier, the process by which that needs to happen, and I agree with the Deputies that it needs to happen, is through the regional health areas because we will be creating the one organisation in each region that is responsible for end-to-end patient care. I go to Galway, meet the nurses, doctors and managers and look at a situation that is not acceptable for patients or our healthcare workers. I am meeting some emergency medicine nurses shortly and I know the committee has been engaged in the same thing. As Deputy Shortall rightly said, the CHO has some responsibility in terms of stopping people from going into hospital in the first place and the GP network has some responsibility in terms of out-of-hours GP cover. Some community hospital care that is under the CHO has responsibility to ensure beds are available. The hospital group has a responsibility to make sure there is correct load balancing and so forth across the different hospitals. The individual hospital is responsible for patients coming in the door but it is reliant on the CHO and nursing homes to a large extent to make sure patients can be discharged. There is no single organisation that I and the committee can meet to ask what the head of organisation is doing and what its executive team is doing to sort this out. I agree with Deputy Shortall but it is well beyond the scope of this legislation. However, I would be very happy to discuss it with the committee on an ongoing basis.

Deputy David Cullinane: I agree with the Minister that it is beyond the scope of this Bill and is a much broader issue. Deputy Shortall spent much time at that meeting with Kerry CAMHS trying to work through the maze of the different management layers to find out who was accountable for what. Her presentation of the responses we got back is accurate. It was impossible for us to work out who was responsible. It seems everybody was and nobody was, as has been said.

As it is not relevant to the scope of this Bill, it might be useful if the Minister could give a commitment that some time over the next number of months, he will come back to this committee regarding the regional health areas, specifically the area of accountability and the changes

that might come about. We all had concerns. I know the Minister rejected some of the concerns we expressed when the two senior officials in the Department and the HSE appeared before us concerning regionalisation. I have concerns about that process, as have other members, but accountability is critical to it.

Integration of healthcare is critical but accountability is also critical. It speaks to one of the areas of this Bill. It is one area of it with regard to mandatory reporting but accountability is much bigger than that and it is a much broader debate that we should have. I ask that we put it on our work schedule. If the Minister is prepared to come in and discuss regional health authorities, accountability and the changes that can and should be made to improve accountability, it would be a really useful and constructive session of the committee. I am pressing the amendment.

Amendment put and declared lost.

Section 7 agreed to.

Sections 8 to 11, inclusive, agreed to.

SECTION 12

Deputy Stephen Donnelly: I move amendment No. 6:

In page 21, between lines 13 and 14, to insert the following:

"(3) The Executive shall have regard to *subsections (1)* and *(2)*—

(a) in the performance of its functions under section 7 of the Act of 2004, and

(b) without prejudice to the generality of *paragraph (a)*, in its management and delivery, under section 7(4) of the Act of 2004, of health and personal social services.

(4) The Authority shall have regard to *subsections (1)* and *(2)* when setting standards referred to in section 8(1)(b) of the Act of 2007.

(5) A professional regulatory body shall have regard to *subsection (2)* in the performance of its functions by or under—

(a) the Medical Practitioners Act 2007,

(b) the Act of 1985,

(c) the Pharmacy Act 2007,

(d) the Act of 2011,

(e) the Act of 2005, or

(f) the Order of 2000.

(6) Without prejudice to the generality of *subsection (5)*, a professional regulatory body shall make provision for the obligation referred to in *subsection (2)* in, having regard to each of the different health practitioners—

(a) the standards of practice or guidance referred to in section 7(2)(i) of the Medi-

cal Practitioners Act 2007,

(b) the guidance referred to in section 66(2) of the Act of 1985,

(c) the codes referred to in section 7(2)(a)(iii) of the Pharmacy Act 2007,

(d) the code referred to in section 9(2)(g)(iii) of the Act of 2011,

(e) the guidance referred to in section 27(3)(c) of the Act of 2005, or

(f) the guidelines referred to in Article 4(o) of the Order of 2000.

(7) In this section—

"Act of 2004" means the Health Act 2004;

"professional regulatory body" means—

(a) in the case of a registered medical practitioner or a medical practitioner referred to in *paragraph (a)* of the definition of "health practitioner", the Council referred to in the Medical Practitioners Act 2007,

(b) in the case of a registered dentist referred to in *paragraph (b)* of the definition of "health practitioner", the Council referred to in the Act of 1985,

(c) in the case of a registered pharmacist or registered pharmaceutical assistant referred to in *paragraph (c)* of the definition of "health practitioner", the Pharmaceutical Society of Ireland referred to in section 5(2) of the Pharmacy Act 2007,

(d) in the case of a registered nurse or registered midwife referred to in *paragraph (d)* of the definition of "health practitioner", the Board referred to in the Act of 2011,

(e) in the case of a registrant referred to in *paragraph (e)* of the definition of "health practitioner", a registration board established by or under the Act of 2005, or

(f) in the case of a person referred to in *paragraph (f)* of the definition of "health practitioner", the Council referred to in the Order of 2000.".

Section 12 addresses openness and transparency and sets out that when making an open disclosure under this Bill, health service providers and health practitioners must provide all relevant information to the patient or to his or her relevant person and where appropriate, any other health service to address the consequences of the notifiable patient safety incident. A Government decision in December 2019 approved the drafting of the head of the following Committee Stage amendment to seek to expand the provisions of this Bill, for example, section 12 regarding openness and transparency - to apply more widely with regard to patient safety incidents.

Following consultation with the Office of the Attorney General, the Department added further draft provisions to section 12. These additional provisions intend to expand the impact of sections 12(1) and (2) under openness and transparency in the Bill by ensuring these provisions are enshrined in the relevant polices, national standards and codes of professional conduct or practice set by the relevant organisations. These are the HSE, as the body responsible for the delivery of health and social services; HIQA, as the body with responsibility for setting national standards for the delivery of those services and monitoring and reporting against those standards; and relevant regulatory authorities such as the Medical Council, the Nursing and Mid-

wifery Board of Ireland and others with responsibility for registration and oversight of specific health practitioners defined in this Bill.

These new provisions seek to enshrine in legislation a need for due regard to the provisions contained in the section on openness and transparency in these policies, national standards and codes of professional conduct. They go further than towards achieving the objective of ensuring the duty of candour is embedded across the health service.

Amendment agreed to.

Section 12, as amended, agreed to.

Sections 13 and 14 agreed to.

SECTION 15

Deputy Stephen Donnelly: I move amendment No. 7:

In page 23, line 12, to delete "in writing".

Amendment agreed to.

Section 15, as amended, agreed to.

Section 16 agreed to.

SECTION 17

Deputy Stephen Donnelly: I move amendment No. 8:

In page 24, lines 35 and 36, to delete "by telephone (or other similar method of communication) ("other than in person")" and substitute "other than in person".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 9:

In page 24, line 38, after "request" to insert "under *subsection (2)*".

Amendment agreed to.

Section 17, as amended, agreed to.

SECTION 18

Chairman: Amendments Nos. 10, 11, 16, 18 and 20 to 24, inclusive, are related and will be discussed together.

Deputy Stephen Donnelly: I move amendment No. 10:

In page 25, to delete lines 21 to 28 and substitute the following:

"(c) shall, in accordance with *section 24*, give the patient or the relevant person (or both of them) a copy of the statement referred to in *subsection (5)*,".

These are minor, technical amendments that will streamline the text in respect of how a copy

of the statement is provided. They will have no material impact on the provisions in the Bill.

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 11:

In page 25, to delete lines 30 to 34 and substitute the following:

"(d) shall give the statement referred to in *section 11(1)* to the patient or relevant person (or both of them) in accordance with *section 24*.".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 12:

In page 27, line 3, to delete "in writing".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 13:

In page 27, line 17, to delete "in writing".

Amendment agreed to.

Section 18, as amended, agreed to.

SECTION 19

Deputy Stephen Donnelly: I move amendment No. 14:

In page 29, line 26, to delete "a request under"

Amendment agreed to.

Section 19, as amended, agreed to.

Section 20 agreed to.

SECTION 21

Chairman: Amendments Nos. 15 and 36 are related and will be discussed together.

Deputy Stephen Donnelly: I move amendment No. 15:

In page 31, line 13, to insert a comma after "(3)".

This minor drafting amendment will insert a comma. Similarly, amendment No. 36 will merely insert the letter "a" before "service provider". The amendments are purely technical, to correct the text. There will be no material impact on the provisions in the Bill.

Amendment agreed to.

Section 21, as amended, agreed to.

SECTION 22

Deputy Stephen Donnelly: I move amendment No. 16:

In page 32, to delete lines 15 to 22 and substitute the following:

"(c) shall, in accordance with *section 24*, give the patient or relevant person (or both of them) a copy of the statement referred to in *subsection (3)*.".

Amendment agreed to.

Section 22, as amended, agreed to.

SECTION 23

Deputy Stephen Donnelly: I move amendment No. 17:

In page 35, line 26, after "*(1)*" to insert "and whether it was requested that the clarification be made other than in person".

Amendment agreed to.

Section 23, as amended, agreed to.

SECTION 24

Deputy Stephen Donnelly: I move amendment No. 18:

In page 37, to delete lines 7 to 16 and substitute the following:

"(2) A health services provider shall—

(a) give the statements referred to in *subsection (1)(a)* to the patient or relevant person (or both of them)—

(i) at the meeting referred to in *subsection (1)(a)*, or

(ii) not later than 5 days from the date on which the meeting referred to in *subsection (1)(a)* was held,

and

(b) give the statement referred to in *subsection (1)(b)* or *(1)(c)*, to the patient or relevant person (or both of them)—

(i) at the meeting referred to in *subsection (1)(b)*, or, as the case may be, at a clarification referred to in *subsection (1)(c)*, or

(ii) not later than 5 days from the date on which the meeting referred to in *subsection (1)(b)*, or, as the case may be, the clarification referred to in *subsection (1)(c)*, was held.".

Amendment agreed to.

Section 24, as amended, agreed to.

SECTION 25

Deputy Stephen Donnelly: I move amendment No. 19:

In page 37, line 39, to delete "in writing".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 20:

In page 38, to delete line 3 and substitute the following:

"(d) the note referred to in *section 19(6)(d)*,".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 21:

In page 38, to delete line 4 and substitute the following:

"(e) the note referred to in *section 19(10)*,".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 22:

In page 38, to delete line 6 and substitute the following:

"(g) the statement referred to in *section 22(5)*,".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 23:

In page 38, line 9, to delete "*section 23(7)*." and substitute "*section 23(7)*, and".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 24:

In page 38, between lines 9 and 10, to insert the following:

"(i) a record of a request (if any) referred to in *section 17(4)* or section *21(9)*.".

Amendment agreed to.

Section 25, as amended, agreed to.

SECTION 26

Chairman: Amendments Nos. 25, 32 and 48 are related and will be discussed together.

Deputy David Cullinane: I move amendment No. 25:

In page 38, to delete lines 20 to 23 and substitute the following:

" "Incident management system" means a system established for the purpose of the reporting, of an adverse incident which may be prescribed from time to time by the Minister in accordance with *section 52*.".

I was seeking to assist the Minister by tabling these amendments. It will change the definition

of "incident management system". HIQA has flagged with us, and I am sure also with the Minister, that it has concerns about the national incident management system, NIMS. We may well have to change the system, and I believe we will. The amendments will mean that, if that is the case, we will not need to amend the Act. Rather, it will be able to be done by way of a regulation brought in by the Minister, as opposed to an amendment to the Act itself. It is better from the point of view of the legislative process to give the Minister that flexibility in order that if there is a change in the type of management system that is in place and if NIMS is to be changed or replaced, the logic of this group of amendments will mean that can be done by way of regulation, rather than require an amendment of the Act, which would not be a good use of our time.

Deputy Stephen Donnelly: I looked carefully at this proposal to see its implications because I appreciate what the Deputy is seeking to achieve, namely, to provide flexibility in regard to the ability to change the system. There are a few issues to consider, one of which relates to how the current system is going. The reports that have come back are good. The Deputy rightly referenced the HIQA review of May of last year. It examined the information management practices for NIMS throughout the HSE. It recommended improvements in the system, as the Deputy highlighted, and the review acknowledged the importance specifically of the NIMS. The review states:

> Incident management plays a vital role in patient safety surveillance and learning. NIMS, as the system underpinning incident management across the public health and social care system in Ireland is therefore an extremely important national health data collection. This review recognises the progress made by the HSE in its efforts to embed NIMS as the single designated national information system for incident management, patient safety, and learning across the HSE and HSE-funded services. HIQA also acknowledges the examples of good information management practices highlighted throughout this review, particularly in relation to information governance and use of information.

The Deputy quite rightly pointed out that there is more to be done. HIQA carried out a very good report on NIMS last year and the HSE is looking to expand it. My concern with the amendments, which is why I cannot accept them even though I fully appreciate the Deputy's intent, is that they could undermine the prospect of us having an all-encompassing national system to be used throughout the country. It is important that the entire HSE and all the publicly funded services use the same system. There is a concern that one unintended consequence of the amendments is that they would give service providers freedom to say they will use something else. I appreciate that is absolutely not what the Deputy intends, but it is a concern. One of the main challenges we have, as has been discussed by all of us at previous committee meetings, relates to the importance of having a single integrated national data management system, rather than the multiplicity of systems we are currently using throughout the health service.

Accordingly, I cannot accept the amendments, although I fully appreciate the intent of them. It is essential to ensure there is no room for individual providers to decide they will adopt a new system, in order that everyone will use the same one.

Deputy David Cullinane: The unintended consequences the Minister mentioned are, obviously, issues we do not want to see happen. I thank him for pointing them out and thank his officials for having studied the amendments. More broadly, NIMS is very important and will continue to be important once the Bill passes and becomes operational. The Minister mentioned the HIQA report of last year. In constructing the Bill and taking account of the issues I have flagged by way of these amendments, has he or any of his officials engaged with HIQA

specifically on its views regarding NIMS? I understand it has concerns. Whether those concerns can be addressed through changes in how NIMS operates may be the issue of debate. If that is the case, that is fine.

This amendment provides for a time when a different system may be put in place. I may be wrong but my understanding is that HIQA would have a view on that matter. I will not speak for HIQA as it is important it speak for itself. Has the Minister or his officials engaged with it? If so, what changes are we looking at with regard to NIMS? What changes will be made to address the concerns raised by HIQA? If those concerns are being addressed, perhaps the amendment is not relevant. Will the Minister outline what proposed changes arise from discussions he has had with HIQA and when they will be made?

Deputy Stephen Donnelly: There has been engagement since the report was published In 2021. This year, it was meant to meet earlier but could not due to Covid.

Deputy David Cullinane: Who was to meet?

Deputy Stephen Donnelly: There is a multi-stakeholder group, which includes representatives of the HSE, HIQA, the Mental Health Commission, the State Claims Agency and the Department of Health. It will reconvene later this week to conclude the work. I will ask the Department to send a note to the committee on the status of that work. The short answer is that HIQA has basically said this is the right way to go but changes are needed. A multi-stakeholder group will meet to ensure that happens. I will ask the Department to provide a technical note to the committee to that effect.

Deputy David Cullinane: A note would be useful. However, this is more about the Minister's acceptance that HIQA has flagged concerns relating to NIMS. The other stakeholders on the multi-stakeholder group may also have concerns. It would be useful for the committee to get a note on what, if any, concerns the group has. I understand it has concerns. The issue then is what action will be taken to address those concerns. It might be more useful to get that clarification from the stakeholder group. We could then get a follow-up letter from the Minister outlining what action may or may not be taken arising from the concerns expressed by the group.

Deputy Stephen Donnelly: That is not a problem.

Deputy David Cullinane: On that basis, I will withdraw the amendment.

Amendment, by leave, withdrawn.

Section 26 agreed to.

SECTION 27

Chairman: Amendment No. 26 is out of order as it is outside the provisions of the Bill.

Amendment No. 26 not moved.

Chairman: Amendments Nos. 27, 29 and 31 are related and may be discussed together.

Deputy David Cullinane: I move amendment No. 27:

In page 38, line 30, to delete "7 days" and substitute "3 days".

These amendments all do exactly the same thing, that is, reduce from seven to three days the

timeframe within which a provider must notify HIQA or the Mental Health Commission that a notifiable incident has occurred. I understand the standard practice across HIQA for notifying incidents is already three days as opposed to seven days. Given the urgency of this, perhaps the Minister will agree that the quicker the notification, the better. Will he explain why the Bill provides for seven days rather than a shorter period? We are seeking to bring in a level of consistency with what already happens and which I believe is standard practice across HIQA and the Mental Health Commission. The amendments seek to reduce the time within which a provider must notify HIQA or the Mental Health Commission of a notifiable incident from seven to three days.

Deputy Stephen Donnelly: We are striving to make the period as short as possible by ensuring the health providers have enough time to do all of the work required. The providers must comply with some serious obligations. There was extensive discussion with health service providers on this matter. The issues raised included staffing over weekends, people being off, shift work and so on. In order that all those who need to make an input can do so and all the information needed for compliance can be gathered, seven days was deemed to be the right balance. It will still be done very quickly while taking account of working patterns.

Deputy David Cullinane: We discussed patient safety advocates and representatives, including issues around the Independent Patient Safety Council. Many patient advocates have their own views about the council, which include the view that it does not work. I will park that for one second. This is an area that should also be kept under review. When we agreed mechanisms and a review of the operation of the Act, we agreed that the Independent Patient Safety Council would do a report at the end of the year or perhaps 12 months after the passing of this legislation. We cannot force it do so but we can certainly ask it to do a report. I assume it would do so and would also look the number of days. If it believed it necessary to reduce the period of seven days, that could be considered. If the Minister is happy to include that in the letter he is sending to the Independent Patient Safety Council, I will be happy to withdraw the amendment.

Deputy Stephen Donnelly: I am very happy to include that in the letter.

Amendment, by leave, withdrawn.

Section 27 agreed to.

SECTION 28

Chairman: Amendment No. 28 is out of order as it involves a potential charge on the Exchequer.

Amendment No. 28 not moved.

Amendment No. 29 not moved.

Chairman: Amendment No. 30 is out of order as it involves a potential charge on the Exchequer.

Amendment No. 30 not moved.

Section 28 agreed to.

SECTION 29

Amendment No. 31 not moved.

Section 29 agreed to.

SECTION 30

Amendment No. 32 not moved.

Section 30 agreed to.

Section 31 agreed to.

SECTION 32

Deputy David Cullinane: I move amendment No. 33

In page 42, line 5, after "functions" to insert the following:

"or to aid in the sharing of information for the purposes of population health information and related matters as the Minister may prescribe by regulation under this section".

Amendment No. 33 seeks to permit HIQA and other bodies to use information gathered under the Act to inform broader pictures of population health and any other purpose which the Minister could provide. This would ensure that information collected by HIQA and other bodies under the Act can be used, where appropriate, rather than having to duplicate work when other bodies require such information. It would be a useful amendment. I am interested in hearing the Minister's response.

Deputy Stephen Donnelly: I fully agree. I checked the position and the issue is already covered. It is wider than HIQA. Section 32(2) provides that any relevant body can use the information provided under this section provided it is relevant to the performance of its functions. I fully agree with the Deputy's position but the advice I have is that this matter is covered already.

Deputy David Cullinane: That is fair enough. I will withdraw the amendment.

Amendment, by leave, withdrawn.

Amendment No 34 not moved.

Section 32 agreed to.

Sections 33 and 34 agreed to.

SECTION 35

Deputy Stephen Donnelly: I move amendment No. 35:

In page 44, to delete lines 10 and 11 and substitute the following:

" "aggregated information", in relation to data, means data obtained from a clinical audit which excludes information that identifies or could reasonably lead to the identification of a person in that clinical audit;".

This is a technical amendment to correct the definition of "aggregated information". The revised definition is "aggregated information", in relation to data, means data obtained from a clinical audit which excludes information that identifies or could reasonably lead to the identification of a person in that clinical audit."

Amendment agreed to.

Section 35, as amended, agreed to.

Sections 36 to 40, inclusive, agreed to.

SECTION 41

Deputy Stephen Donnelly: I move amendment No. 36:

In page 49, line 21, to delete "service provider" and substitute "a service provider".

Amendment agreed to.

Section 41, as amended, agreed to.

SECTION 42

Chairman: Amendments Nos. 37 to 41, inclusive, are related and may be discussed together.

Deputy Stephen Donnelly: I move amendment No. 37:

In page 50, lines 17 and 18, to delete "of the services" and substitute "of any of the services".

I will speak to amendments Nos. 37 to 41, inclusive. I am introducing an amendment to section 9 of the Health Act 2007 to clarify and strengthen the powers to direct an investigation into Ireland's health and social services by the Health Information and Quality Authority, HIQA. Section 9 of the Health Act 2007 gives the Minister for Health and Minister for Children, Equality, Disability, Integration and Youth the power to direct HIQA to undertake a statutory investigation to address serious ongoing risks to patient safety in Ireland's health and social services.

In the National Maternity Hospital *v.* the Minister for Health in September 2018, the court quashed a decision by the then Minister for Health to direct HIQA to carry out a section 9 investigation into a maternal death that had occurred at the hospital. The central difficulty in this case addressed in the judgment and by counsel throughout was the very high bar set by section 9 of the Health Act for ordering such an investigation under this section. It is clear from the judgment and from legal advices received that the current discretion for the ordering of an investigation under section 9 is extremely limited and impractical in terms of allowing for an appropriate response to ongoing risk to patient safety within our health and social services.

The proposed amendments to section 9 of the Health Act 2007 will ensure that when directing an investigation into Ireland's health and social services, the Ministers and-or HIQA must believe on reasonable grounds that there may be serious risk to the health or welfare of people receiving services that will be the subject of investigation. This replaces the previous requirement for a belief there is a serious risk.

Second, there may be a section 9 investigation into a specific service, notwithstanding that

a similar risk may exist in another service. Third, the purpose of the investigation will include a public interest element where a need for learning and improvement of services will form part of the rationale for requiring an investigation under section 9. The provisions are repeated for both the Minister for Health and Minister for Children, Equality, Disability, Integration and Youth. References in the Bill are to the Minister for Children and Youth Affairs and these will subsequently be updated with the new title.

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 38:

In page 50, line 20, to delete "and".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 39:

In page 50, to delete lines 21 to 29 and substitute the following:

"(ii) by the substitution of the following paragraph for paragraph (a):

"(a) there may be a serious risk—

(i) to the health or welfare of a person receiving those services, or

(ii) of a failure to comply with the provisions of the Act of 2013, notwithstanding that such a risk may also exist elsewhere in those services,",

and

(iii) by the substitution of the following paragraph for paragraph (b):

"(b) the risk may be the result of any act, failure to act or negligence on the part of—

(i) the Executive,

(ii) the Agency,

(iii) a service provider to which paragraph (a) or (b) of the definition of service provider applies,

(iv) a service provider to which paragraph (c) of the definition of service provider applies,

(iva) a service provider to which paragraph (d) of the definition of service provider applies,

(v) the registered provider of a designated centre to which paragraph (a)(ii), (iii) or (c) of the definition of designated centre applies,

(vi) the registered provider of a designated centre to which paragraph (a)(i) or (b) of the definition of designated centre applies,

(vii) the person in charge of a designated centre referred to in subparagraph

(v), if other than its registered provider,

(viii) the person in charge of a designated centre referred to in subparagraph (vi), if other than its registered provider, or

(ix) a person carrying on the business of providing a prescribed private health service, and",

and

(iv) by the insertion of the following paragraph after paragraph (b):

"(c) an investigation may be in the interests of—

(i) improving the safety, quality and standards of the services described in section 8(1)(b) or (1)(ba) which are the subject of the investigation, or

(ii) the provision of health and personal social services for the benefit of the health and welfare of the public.",".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 40:

In page 50, to delete lines 33 and 34 and substitute the following:

"(c) by the substitution of the following subsection for subsection (2):

"(2) The Minister may, if he or she believes on reasonable grounds that—

(a) there may be a serious risk of the kind mentioned in paragraph (a) of subsection (1), notwithstanding that such a risk may also exist elsewhere in those services,

(b) the risk may be the result of any act, failure to act or negligence of the kind mentioned in paragraph (b)(i), (iii), (iva), (v), (vii) or (ix) of subsection (1), and

(c) an investigation may be in the interests of—

(i) improving the safety, quality and standards of the services described in section 8(1)(b) or (1)(ba) which are the subject of the investigation, or

(ii) the provision of health and personal social services for the benefit of the health and welfare of the public, require the Authority to undertake an investigation in accordance with this section.",".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 41:

In page 50, to delete lines 35 to 37 and substitute the following:

"(d) by the substitution of the following subsection for subsection (2A):

"(2A) The Minister for Children and Youth Affairs may, if he or she believes on reasonable grounds that—

(a) there may be a serious risk of the kind mentioned in paragraph (a)(i) of subsection (1), notwithstanding that such a risk may also exist elsewhere in those services,

(b) the risk may be the result of any act, failure to act or negligence mentioned in paragraph (b)(ii), (iv), (vi) or (viii) of subsection (1), and

(c) an investigation may be in the interests of—

(i) improving the safety, quality and standards of the services described in section 8(1)(b) or (1)(ba) which are the subject of the investigation, or

(ii) the provision of health and personal social services for the benefit of the health and welfare of the public, require the Authority to undertake an investigation in accordance with this section.","

Amendment agreed to.

Section 42, as amended, agreed to.

Sections 43 to 45, inclusive, agreed to.

SECTION 46

Chairman: Amendments Nos. 42 to 45, inclusive, are related and may be discussed together.

Deputy Stephen Donnelly: I move amendment No. 42:

In page 53, to delete lines 6 and 7 and substitute the following:

"(2) A report prepared under subsection (1) may include information on—

(a) the monitoring of compliance with standards under section 8(1)(c),

and

(b) any investigation carried out under section 9.".

Amendments Nos. 42 to 45, inclusive, relate to the publishing of reports by HIQA. The amendments will strengthen HIQA's ability to publish reports relating to its monitoring programmes and investigations carried out in accordance with section 8(1)(*c*) and section 9 of the amended Health Act 2007.

It is important that we protect HIQA's ability to publish reports relating to its investigations and monitoring programmes while at the same time ensuring the subject of these reports have a right to reply in line with fair procedure processes. The amendments ensure there is uniformity across all service providers in relation to the publication of reports and application of a fair procedure process.

Deputy Róisín Shortall: I would like to tease this out a little bit. We had two very stark examples in the recent past of reports being produced on poor practice, let us say. The reports, namely, the Grace report and Brandon report, have not been published. People are still waiting for those. We were told both of those reports could not be published because they were being

referred on to the Garda. They were referred and then the recommendation was that no action would be taken. I think in one case, the recommendation was from the Director of Public Prosecutions.

What would change that in terms of what the Minister is proposing in these amendments? Does he see grounds for not publishing a report in any circumstances where there have been adverse incidents or particular scandals? We are trying to get our hands on those reports and it is very hard to understand why neither of those have been published to date. What is the Minister's view on that? Will these amendments allow for those reports to be published?

Deputy Stephen Donnelly: I agree; I think there is an issue. We should always err on the side of transparency. Obviously, we must protect individuals. Many of these reports are very sensitive but that can be done largely through redaction and anonymisation. I am not comfortable with important reports that have a public interest not being published as soon as possible.

These amendments help and would speak to any section 9 HIQA report. I am very happy to provide the committee with a note as to exactly which reports they would be. These amendments move some way in the direction the Deputy outlined in that they strengthen HIQA's ability to do exactly what she referenced in terms of the reports. I will need to check on the two very specific reports the Deputy referenced. If she bears with me, I will check if those specific reports would be covered. If it is okay with the Deputy and Chairman, I will ask the Department to furnish a more detailed note to the committee on exactly the scope of the reports that would and would not be covered.

Deputy Róisín Shortall: I appreciate that. I thank the Minister for that clarification. Perhaps when his asks the Department to prepare that note, for general information for the committee, the Minister might also ask it to produce a note on the reasons those two reports I mentioned are not being published.

Deputy Stephen Donnelly: That is no problem at all.

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 43.

In page 53, lines 10 and 11, to delete "a service provider or a person carrying on the business of providing a prescribed private health service" and substitute the following:

> "the Executive, the Agency, a service provider, a person carrying on the business of providing a prescribed private health service, or the registered provider of a designated centre or the person in charge of that designated centre if other than its registered provider".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 44:

In page 53, line 20, to delete "the draft report and shall furnish" and substitute "the draft report and, prior to publication, shall furnish".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 45:

In page 53, to delete lines 23 to 25 and substitute the following:

"(c) a service provider,

(d) a person carrying on the business of providing a prescribed private health service, or

(e) the registered provider of a designated centre or the person in charge of that designated centre if other than its registered provider."

Amendment agreed to.

Section 46, as amended, agreed to.

Sections 47 and 48 agreed to.

SECTION 49

Chairman: Amendments Nos. 46 and 47 are related and may be discussed together.

Deputy David Cullinane: I move amendment No. 46:

In page 55, line 1, to delete "or *29*" and substitute ", *29* or *30*".

I will first withdraw amendment No. 46 because it is a technical amendment and some of the issues were discussed earlier.

Amendment No. 47 provides that HIQA may be the prosecuting body under the Act for the provisions that relate to it. As the Minister will be aware, some incidents might not be a priority for the Garda or other bodies. Obviously, not all incidents are referred on to An Garda Síochána. HIQA is the expert and regulatory body in the context of these incidents and it should be the body that is able to prosecute offences under the Act.

The amendment also provides for the Minister to prescribe a body, whether that is HIQA or another body, to prosecute under various sections of the Act as may be appropriate and, where such an alternative body is not prescribed, to ensure it falls by default to An Garda Síochána. The purpose of the amendment is to ensure that where incidents are not reported to An Garda Síochána and it does not fall to it to prosecute, it appropriately falls to HIQA or another body as prescribed by the Minister to do so under the Act. That would be an appropriate way to deal with these issues. I will be pressing the amendment. Obviously, I am interested to hear the response of the Minister.

Deputy Stephen Donnelly: I thank the Deputy for tabling the amendment. I do not intend to accept it, not because I disagree with much of what the Deputy has said but because I carefully considered this and the advice I have is that the specific provision is not required in the Bill to allow An Garda Síochána to prosecute the offences under the Act. Regulators such as HIQA, the chief inspector and the Mental Health Commission all have distinct roles and responsibilities, as the Deputy outlined, in terms of regulating health and social services and they already have functions set out in the Bill. It is important there is clarity in respect of the functions and respective roles of the regulators. It is particularly relevant in this context as no one regulator covers all of the health and social service providers that are subject to the Bill. Prosecution of these types of offences would represent a significant increase and change in their respective functions and, with that in mind, the advice I have and with which I agree is that the Garda is

best placed and has the appropriate powers to carry out investigations and bring proceedings in the event of an event having been committed under the Act.

Deputy David Cullinane: I ask the Minister to clarify whether it is only the Garda Síochána that can prosecute under the Act.

Deputy Stephen Donnelly: Yes, it is.

Deputy David Cullinane: I have a concern about that. It is not that I do not believe An Garda Síochána should carry out such prosecutions. Rather, my concern is that some of the incidents may not be a priority for the Garda. In terms of scale, some incidents will be more serious than others. I believe a better, more effective and more efficient way to do it would be for HIQA and other bodies to also have the power to prosecute. In my view, that would strengthen the operation of the Act. I have a concern that the only prosecuting body will be An Garda Síochána. It remains to be seen how it will work in practice. The Minister has given his rationale. I accept that is the position of the Department. I will be pressing the amendment but I will not push it to a vote.

Amendment, by leave, withdrawn.

Section 49 agreed to.

NEW SECTION

Deputy David Cullinane: I move amendment No. 47:

In page 55, between lines 17 and 18, to insert the following:

"Proceedings for Offences

50. Summary proceedings for an offence under this Act may be brought and prosecuted—

(a) where a person contravenes *section 27, 28, 29*, or *30*, by the Authority,

(b) in any other case, by the appropriate body which may be prescribed by the Minister for time to time in accordance with this Act,

(c) in any case where such an alternative body is not prescribed, by an Garda Síochána.".

Amendment put and declared lost.

Sections 50 and 51 agreed to.

Amendment No. 48 not moved.

Sections 52 to 54, inclusive, agreed to.

NEW SECTION

Deputy David Cullinane: I move amendment No. 49:

In page 56, after line 27, to insert the following:

"Report of the Minister

55. (1) Not later than 2 months after receiving a Report of the Patient Safety Council, the Minister shall lay the Report of the Patient Safety Council and a Report of the Minister before the Houses of the Oireachtas in accordance with *subsection (2)*.

(2) The Report of the Minister shall include:

(a) the response of the Minister to each of the recommendations of the Report of the Patient Safety Council;

(b) the intentions of the Minister to bring forward amendments to give effect to the recommendations of the Patient Safety Council;

(c) the number and nature of notifiable incidents reported to the relevant bodies in the preceding year and since the passage of the Act;

(d) the additional resources sought by the Authority, Commission, and other relevant bodies for the full and effective implementation of the Act;

(e) the actual additional resources provided to said bodies following requests for additional resources;

(f) details of engagements with the Authority and the Patient Safety Council for the strengthening of this Act, the Act of 2007, and progressing adult safeguarding legislation;

(g) any additional powers sought by the Authority or any other body for the effective implementation of this Act.".

The amendment is self-explanatory. I am sure the Minister has read it. It is basically to improve reporting. It provides, "Not later than 2 months after receiving a Report of the Patient Safety Council, the Minister shall lay the Report of the Patient Safety Council and a Report of the Minister before the Houses of the Oireachtas". This relates to other amendments that have already fallen. It goes back to the discussion we had earlier about the role of the patient safety council. The Minister has already accepted that a letter will go from his office to ask that it report within a reasonable period after the passage of the Bill. On that basis, I will withdraw the amendment.

Amendment, by leave, withdrawn.

SCHEDULE 1

Chairman: Amendment No. 50 is out of order as it involves a potential charge on the Revenue.

Amendment No. 50 not moved.

Question proposed: "That Schedule 1 be a Schedule to the Bill."

Deputy David Cullinane: I tabled amendment No. 50 because, as all present are aware, the issue of delayed diagnosis was among those at the core of the failures in the context of CervicalCheck. Is the Minister comfortable with delayed diagnosis not being one of the notifiable

incidents? For me, it is an obvious area that should be included. I am interested in hearing the Minister's reasons for it not being included. I am not sure why the amendment was ruled out of order on the basis of putting a cost on the Exchequer. That does not make sense to me. The Minister cannot respond on the amendment but I ask that he provide his rationale for delayed diagnosis not being included in the Schedule as a notifiable incident, given what happened in CervicalCheck and that delayed diagnosis was so central to many of the concerns and failures relating to open disclosure.

Deputy Stephen Donnelly: I agree with much of what the Deputy has said, including in the context of CervicalCheck. I carefully considered the amendment and whether this particular incident could be included as a notifiable event. We looked around the world and could not find any system that includes this specific incident. The rationale is that it is vague. Many of the notifiable incidences are quite binary. They relate to things that clearly happened and it is clear to see what they are. Delayed diagnosis is quite vague. Its inclusion would essentially create an unsupportable administrative burden on the entire system. It could cover anything from relatively minor delays to much more serious ones, including those such as the ones the Deputy referenced. As it stands, the current list of notifiable events is specifically designed to cover the most serious reportable events, that is, those that cause death or serious injury. These notifiable patient safety events set out currently in the Bill are clearly defined and provide clear direction to health service practitioners.

However, as I stated in my opening remarks, I will bring forward on Report Stage an amendment that deals with the incidences we all discussed at great length and that were flagged through everything that happened with CervicalCheck. The advice I have is that it is legally and technically very difficult to do. A significant amount of work has been done to figure out a way to do it and there are ongoing discussions on it. I am seeking to address this issue through an amendment I will bring forward on Report Stage. As regards the specific question of whether we could just have added it to the Schedule, the advice I have is that would not work. It would not be practicable for all the reasons I have laid out.

Deputy David Cullinane: If I may respond to the Minister, one of the reasons he may not be able to find it anywhere internationally is that there may not have been the same level of incidents in cancer screening and cervical check screening in other countries as occurred in Ireland. Unfortunately, we have direct experience in this State of how women were failed. One of the reasons open disclosure and mandatory reporting is on our agenda is because of what happened to many of those women in terms of failures to report and issues relating to open disclosure. There have been many more incidents. Obviously, it was not only related to CervicalCheck, although it was cited in Dr. Scally's report in the recommendations he made that we move to implement in this area. I accept what the Minister is saying that he has got advice, that it would not be appropriate to add it to the Schedule and that he will bringing forward an amendment on Report Stage that will deal with this and with broader issues relating to the failures that happened in CervicalCheck. I look forward to what that means, what it will look like and what it will do. We will evaluate that when we see it. For me, this is a really important area. If I were to push any amendment to a vote, it would be this one. On the basis of what the Minister said, that he will bring forward an amendment on Report Stage, and to be fair to the Minister and his officials, they appear to have done much good work in this area, reluctantly, I will withdraw my amendment. If the Minister was able to forward to the committee, as soon as possible, a note on what that amendment may seek to do or a copy of the amendment when drafted, it is important we get sufficient notice of it in order that we can go through it. The amendment the Minister will bring forward is a critical one. On that basis, I will withdraw the amendment or, apologies,

it cannot be withdrawn as it was ruled out of order.

Chairman: It has been ruled out of order. People want to speak to Schedule 1.

Deputy Róisín Shortall: I very much accept what the Minister is saying. It is an exceptionally complex area to legislate for. In preparing the Report Stage amendment, can the Minister indicate if it will deal with the specific area of screening or is it a wider issue? In terms of trying to be specific about shortcomings in screening programmes, it is hard to do that. There are many implications then for the viability of screening programmes. Is that what the Minister has in mind, that he intends to legislative specifically for screening programmes?

Deputy Stephen Donnelly: Yes. That is right. I have had lengthy discussions with the Department on this. It does not fit neatly with this Bill. The serious patient safety issues which result in death or serious harm are very clear. They are binary, for example, where someone had something done to them in an operation which should not have been done or whatever it might be. As the Deputy said, legislating around delayed diagnosis screening support is complex. It does not fit neatly in this Bill. However, my view, and I imagine it is one we all share, is that the non-disclosure that happened in CervicalCheck, even though it does not neatly fit here, should still be legislated for. I have asked the Department to find a way to do that. Extensive work has been done already and very extensive work is going on now.

In response to Deputy Cullinane's point, I will share the thinking I have on this with the committee. It is something of an add-on, to be honest. It does not fit with the framework we have here. This is our opportunity to make sure we are very clear under law that the element of non-disclosure that happened in CervicalCheck will now be covered under legislation.

Deputy David Cullinane: What Report Stage amendment is the Minister considering?

Deputy Stephen Donnelly: That is what is being worked through at the moment.

Deputy David Cullinane: There would not be a separate item of legislation.

Deputy Stephen Donnelly: No. We will add something to this Bill.

Deputy Róisín Shortall: Will that relate to a situation like we had in CervicalCheck where when the outcomes of the screening programmes were audited, which is desirable, and that information emerged, there was the failure to disclose that. Is that the scenario the Minister is talking about legislating for?

Deputy Stephen Donnelly: Yes, essentially. The expert reference groups on interval cancer are involved in this. It is tricky because there can be a discordance that was flagged. The discordance may or may not have been due to negligence. It might be just, unfortunately as we have all become painfully aware, due to the limitations of the system. A discordance, in and of itself, is not necessarily a patient safety incident, which is why it does not neatly fit here. Essentially, what we are seeking is that where a discordance has been identified, where it is an identified patient - it cannot be done on the anonymised audits - and that patient seeks a look-back and a discordance was found, it would become a legal obligation to disclose to the patient that a discordance was found. The reason it does not fit neatly in here is that discordance may or may not end up having been a patient safety incident but for all the reasons we are very aware of, this is the opportunity to specifically address what happened and say that cannot ever happen again.

Deputy Róisín Shortall: Can I tease that a little more? Is the Minister saying that it would

only be covered in circumstances where there was a patient safety issue in terms of an actual event as opposed to a diagnosis not happening due to perhaps shortcomings in the screen programmes? I would have thought the key issue is not that something goes wrong, which it can do from time to time, but how it is handled and the need for open disclosure on information that comes to light subsequently to, say, a screening programme?

Deputy Stephen Donnelly: Yes, exactly. It is going much further than having to have established that a patient safety event happened. It comes before that. I ask the members to bear with me because there is a lot of work going on to figure out exactly how this will work. Essentially, what I have asked the Department is what the Deputy has just laid out. If we have an identified patient on an interval cancer where a look-back is done and a discordance has been found, regardless of whether that discordance subsequently happens to be a patient safety incident - it may or may not be - open disclosure is required under law.

Deputy Róisín Shortall: I thank the Minister for that. That is good.

Schedule 1 agreed to.

SCHEDULE 2

Chairman: Amendments Nos. 51 to 54, inclusive, are related and will be discussed together.

Deputy Stephen Donnelly: I move amendment No. 51:

In page 59, to delete line 2 and substitute "*Section 53*".

I will speak to amendments Nos. 51 to 54, inclusive. They are technical amendments to align the two items of legislation and ensure there is no discrepancy from a procedural perspective. They do not introduce any new substantive provisions to either Bill. The Civil Liability (Amendment) Act 2017 will continue to outline the process for open disclosure for clinicians who wish to avail of the legal protections that legislation extends to them while the Patient Safety (Notifiable Patient Safety Incidents) Bill will provide for mandatory open disclosure and external notification of certain serious patient safety incidents outlined in Schedule 1 to that Bill.

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 52:

In page 59, to delete lines 13 to 16 and substitute the following:

"

3.	Section 7(1)	The insertion of the following definitions: " 'notifiable incident' has the meaning assigned to it by the Patient Safety (Notifiable Patient Safety Incidents) Act 2022; 'other than in person', in relation to an open disclosure meeting, an additional information meeting or a clarification given under section 19, means holding such meeting or such clarification by means of the telephone or the internet (or other similar method of communication); "

".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 53:

In page 64, between lines 10 and 11, to insert the following:

“

10.	Section 15(1)(f)	By the substitution for paragraph (f) of the following paragraph: “(f) having regard to the information available, make arrangements for the preparation of the statement referred to in section 16(5), that is to be provided, in accordance with section 16(2)(c) to the patient or relevant person (or both of them).”.
11.	Section 15A (inserted by section 53 of the Patient Safety (Notifiable Patient Safety Incidents) Act 2022)	By the insertion of the following section after section 15: “Open disclosure meeting generally to be held in person 15A. (1) An open disclosure meeting shall, subject to subsection (2), be held in person with the patient or relevant person (or both of them). (2) A patient or relevant person (or both of them) may, when contacted by a health services provider pursuant to section 16 to make arrangements to meet with it for the purpose of making an open disclosure, request the provider that the proposed meeting be held other than in person. (3) A request under subsection (2) may be made orally. (4) Where a request under subsection (2) is made orally, the health services provider shall make a record of the request in writing and maintain it with the records referred to in section 21.”.
12.	Section 16(1)(b)	To substitute the following paragraph for paragraph (b): “(b) where a patient or a relevant person has (or both of them have) made a request under section 15A, to hold the meeting other than in person,”.
13.	Section 16(2)(c)	To substitute the following paragraph for paragraph (c): “(c) shall, in accordance with section 20A, give the patient or the relevant person (or both of them) a copy of the statement referred to in subsection (5), and”. 14. Section 16(2)(d) To substitute the following paragraph for paragraph (d):

14.	Section 16(2)(d)	To substitute the following paragraph for paragraph (d): "(d) shall give the statement referred to in section 11(1) to the patient or relevant person (or both of them) in accordance with section 20A or, in the case of a meeting referred to in subsection (1)(b), shall give that statement to the patient or relevant person (or both of them) in accordance with section 20A.".
15.	Section 16(5)(a)	To delete paragraph (a).

".

Amendment agreed to.

Deputy Stephen Donnelly: I move amendment No. 54:

In page 64, after line 25, to insert the following:

"

17.	17(3)(a)	In section 17(3), in paragraph (a), to delete ", in the prescribed form,".
18.	18. Section 17(3) new paragraph inserted	In section 17(3), to insert the following paragraph after paragraph (a): "(aa) include, in the statement referred to in paragraph (a), a reference to the entitlement under subsection (7) for the patient to make a later request for an open disclosure meeting despite the refusal referred to in subsection (2),".
19.	Section 17(5)(a)	In section 17(5), in paragraph (a), to delete ", in the prescribed form,".
20.	Section 17(5) new paragraph inserted	To insert the following new paragraph after paragraph (a): "(aa) include, in the statement referred to in paragraph (a), a reference to the entitlement under subsection (7) for the patient to make a later request for an open disclosure meeting despite the refusal referred to in subsection (4),".
21.	Section 17(6)(i)	In section 17(6), in paragraph (i), to delete ", in the prescribed form,".
22.	Section 17(6)	In section 17(6), after paragraph (i), to insert the following new paragraph: "(ia) include, in the note referred to in paragraph (i), the incident to be disclosed and the date of the incident (if known),".
23.	Section 17(6)(iii)	In section 17(6), in paragraph (iii), to substitute "paragraph" for "subparagraph" in each place where it occurs.
24.	Section 17 new subsections inserted	In section 17, to insert the following new subsections after subsection (6): "(7) Where a patient or a relevant person has, or, as the case may be, both of them have, refused to engage with the health services provider in the making of an open disclosure of a patient safety incident, the patient may, within 5 years from the date of the refusal, request the health services provider to make the open disclosure. (8) A request referred to in subsection (7) may be made orally and the provider shall keep a note of the request in writing specifying the date of the request and the person who made it. (9) Where the health services provider receives a request under subsection (7), it shall hold an open disclosure meeting. (10) The health services provider shall keep, in the records referred to in section 21, the note referred to in subsection (8).".

25.	Section 18 new subsections inserted	In section 18, to insert the following subsections after subsection (1): "(1A) An additional information meeting shall, subject to subsection (1B), be held in person with the patient or relevant person (or both of them). (1B) A patient or a relevant person (or both of them) may, when requesting the holding of an additional information meeting, request the provider that the proposed meeting be held other than in person. (1C) A request under subsection (1B) shall be made orally. (1D) Where a request is made orally under subsection (1C), the health services provider shall make a note, in writing, of the request and it shall be kept in the records referred to in section 21.".
26.	Section 18(3)(b)	In section 18(3), to substitute the following paragraph for paragraph (b): "(b) where the patient or relevant person has made a request under subsection (1B), to hold the meeting other than in person,".
27.	Section 18(4)	In section 18(4), to substitute the following paragraph for paragraph (c): "(c) shall, in accordance with section 20A, give the patient or the relevant person (or both of them) a copy of the statement referred to in subsection (6).".
28.	Section 18(6)(a)	In section 18(6), to substitute the following paragraph for paragraph (a): "(a) be in writing,".
29.	Section 19(1)	Section 19(1) is amended by the substitution of the following for paragraph (b): "(b) any additional information provided to the patient or relevant person (or both of them) at the additional information meeting, and may request that the clarification be made other than in person.".
30.	Section 19(2)(e)(i)	In section 19(2), in paragraph (e)(i), to delete ", in the prescribed form".
31.	Section 19(2)(e)(i)(I)	In section 19(2), in paragraph (e)(i), in clause (I), after "subsection (1)" to insert "and whether it was requested that the clarification be made other than in person".
32.	Section 19(3)(b)	In section 19(3), in paragraph (b), to substitute "shall, in accordance with section 20A, give" for "shall give".
33.	Section 19(5)(a)	Section 19(5) is amended by the deletion of paragraph (a).
34.	Section 20(4)(a)	In section 20(4), in paragraph (a), to delete "in the prescribed form,".

35.	Section 20 new subsection inserted	To insert the following subsection after subsection (4): “(4A) Where, at any time after the signing of the statement referred to in subsection (4)— (a) the health services provider makes contact with the patient or the relevant person, or, as the case may be, both of them, or (b) the patient or relevant person makes, or, as the case may be, both of them make, contact with the health services provider, the health services provider shall hold an open disclosure meeting in order to make the open disclosure of the patient safety incident after that contact has been made.”.

36.	Section 20A (inserted by section 53 of the Patient Safety (Notifiable Patient Safety Incidents) Act 2022)	By the insertion of the following section after section 20:"Statements specifying information given at certain meetings 20A. (1) Subsection (2) shall apply for the purposes of— (a) an open disclosure meeting that is held in person and the provision of the statement referred to in section 16(5) to a patient or relevant person (or both of them) in accordance with section 16(2) (c) and the statement referred to in section 16(2)(d), (b) an additional information meeting that is held in person and the provision of the statement referred to in section 18(6) to a patient or relevant person (or both of them) in accordance with section 18(4), and (c) a clarification provided under section 19 and the provision of the statement referred to in section 19(3)(b) to a patient or relevant person (or both of them) in accordance with that section. (2) A health services provider shall— (a) give the statements referred to in subsection (1)(a) to the patient or relevant person (or both of them)— (i) at the meeting referred to in subsection (1)(a), or (ii) not later than 5 days from the date on which the meeting referred to in subsection (1) (a) was held, and (b) give the statement referred to in subsection (1) (b), or (1)(c), to the patient or relevant person (or both of them)— (i) at the meeting referred to in subsection (1)(b), or, as the case may be, at a clarification referred to in subsection (1)(c), or (ii) not later than 5 days from the date on which the meeting referred to in subsection (1)(b), or, as the case may be, the clarification referred to in subsection (1)(c), was held. (3) Subsection (4) shall apply for the purposes of— (a) an open disclosure meeting that is held other than in person and the provision of the statement referred to in section 16(5) to a patient or relevant person (or both of them) in accordance with section 16(2) (c) and the statement referred to in section 16(2)(d), (b) an additional information meeting that is held other than in person and the provision of the statement referred to in section 18(6) to a patient or relevant person (or both of them) in accordance with section 18(4), and (c) a clarification provided under section 19 that is made other than in person and the provision of the statement referred to in section 19(3)(b) to a patient or relevant person (or both of them) in accordance with that section. (4) A health services provider shall give— (a) the statements referred to in subsection (3)(a) to the patient or relevant person (or both of them) not later than 5 days from the day on which that meeting was held,and (b) the statement referred to in subsection (3)(b) or (3)(c) to the patient or relevant person (or both of them) not later than 5 days from the day on which the meeting referred to in subsection (3)(b), or, as the case may be, the clarification referred to in subsection (3)(c), was held.".
37.	Section 21(1)(b)	To delete "in writing".
38.	Section 21(1) new paragraph inserted	In section 21(1), to insert the following paragraph after paragraph (d): "(da) the request referred to in section 17(10),".
39.	Section 21(1)(f)(ii)	To delete "and".
40.	Section 21(1)(g)	To delete "section 20(4)(c)." and substitute "section 20(4)(c), and".

41.	Section 21(1) new paragraph inserted	To insert the following new paragraph after paragraph (g): "(h) a record, or note, as the case may be, of a request (if any) referred to in section 15A(4) or 18(1D).".

".

Amendment agreed to.

Schedule 2, as amended, agreed to.

Title agreed to.

Bill reported with amendments.

Message to Dáil

Chairman: In accordance with Standing Order 101, the following message will be sent to the Clerk of the Dáil:

The Select Committee on Health has completed its consideration of the Patient Safety (Notifiable Patient Safety Incidents) Bill 2019 and has made amendments thereto.

The select committee adjourned at 11.22 a.m. *sine die.*