REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Dr Ian HUDSON, Chief Executive, Medicines & Healthcare Products Regulatory Agency** **2. Mr Roland DIGGELMANN, Chief Executive, Roche Diagnostics Limited** **3. Dr Andrew GOODHALL, Chief Executive NHS Wales** **4. Mr Simon STEVENS, Chief Executive NHS England**
1	**CORONER** I am Andrew Roger BARKLEY, Senior Coroner for the coroner area of South Wales Central.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 27th January 2016 I commenced an investigation into the death of James Michael HEDGE aged 18. The investigation concluded at the end of the inquest on 6th July 2016. The conclusion of the inquest was that of a narrative conclusion and the medical cause of death was 1a.Diabetic Ketoacidosis. The narrative conclusion was "James Michael HEDGE died from the effects of diabetic ketoacidosis in circumstances in which he had high blood sugar levels and there was a leakage in the insulin pump he was using. The most likely cause of that was the incorrect usage of the machine.
4	**CIRCUMSTANCES OF THE DEATH** James Michael HEDGE was a type 1 insulin dependent diabetic and had been from the age of three. After concern for his welfare, his room at Cardiff University was entered and he was discovered deceased on his bed. It was noted by one of the attending officers that an insulin pump, which was connected to him, was "beeping" A subsequent investigation of the pump revealed that the insulin cartridge had been fitted incorrectly and had leaked.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

	The **MATTERS OF CONCERN** are as follows. – (1) The evidence showed that the advice and guidance in relation to the use of the insulin pump, which is one of several on the market, does not adequately highlight the dangers of misuse and the potential consequences which may follow if the device is not used correctly – in this case, the incorrect insertion of the insulin cartridge leading to a leak and loss of insulin at a time when blood sugars were high. (2) The evidence showed that the education of diabetic patients does not adequately focus upon the potential consequences of failing to properly manage a hyperglycaemic state and in particular, how quickly such a state can become life threatening.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 15 September 2016. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner. Copies have also been sent to: [redacted] parents of James Michael HEDGE Mr Chris ASKEW, Chief Executive of Diabetes UK Mr Mark DRAKEFORD AM, Minister for Health, Welsh Government
9	**27 July 2016** **SIGNED:** **Mr Andrew BARKLEY** **Senior Coroner** **South Wales Central**