REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **Mr Matt Hancock** **Secretary of State** **Department of Health and Social Care** **39 Victoria Street** **London** **SW1H 0EU**
1	**CORONER** I am Nigel Parsley, Senior Coroner, for the coroner area of Suffolk.
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 3rd August 2017 I commenced an investigation into the death of **Deborah Michelle HEADSPEATH** The investigation concluded at the end of the inquest on 11th November 2019. The conclusion of the inquest was that the death was the result of:- **Debbie Headspeath died of a medical condition (aspiration pneumonitis) caused by an inflammation of the pancreas (pancreatitis). The inflammation to Debbie's pancreas was a direct result of the uncoordinated availability of codeine medication which she sourced from multiple prescription-only medication suppliers.** The medical cause of death was confirmed as: **1a Aspiration pneumonitis** **1b Acute on chronic pancreatitis** **1c Chronic codeine use**
4	**CIRCUMSTANCES OF THE DEATH** Debbie Headspeath was a 41-year-old woman who died suddenly on the 28th July 2017 at her home address of 252 Woodbridge Road, Ipswich in Suffolk. Debbie's death was the result of her suffering from a condition called pancreatitis (inflammation of the pancreas). This condition arose due to Debbie's long-standing dependence on the medicinal drug codeine. Debbie's dependence started in 2008 when she was first prescribed dihydrocodeine for back pain by her GP. Due to Debbie's long-term dependence she had developed a tolerance to codeine and therefore needed to take much higher quantities than is normally prescribed. Initially Debbie purchased large quantities of over-the-counter medication which contained both codeine and larger quantities of either Ibuprofen or Paracetamol. Due to the known toxic effects of these drugs her GP prescribed her high doses of codeine so she could avoid taking toxic quantities of Ibuprofen or Paracetamol.

	The GP prescribed codeine proved insufficient in meeting Debbie's dependent need, so she continued to supplement her prescription with additional over-the-counter medication containing codeine. At some point before late 2016, Debbie identified that she could obtain additional codeine tablets 'on-line' and obtained prescriptions of this drug from on-line suppliers. Due to there being no central record of these prescriptions, and the way Debbie herself identified how to manipulate the systems in place, she was able to obtain significant quantities of codeine. In just the last six months prior to Debbie's death, investigations revealed she had received significant quantities of codeine from 16 different on-line suppliers in addition to that prescribed by her GP. Debbie's access to significant quantities of codeine with no coordinated and therefore no effective medical supervision directly led to her death.
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 could occur unless action is taken. In the circumstances it is my statutory duty to report to you; the **MATTERS OF CONCERN** as follows. – During the inquest evidence was heard from the Care Quality Commission national advisor on clinical matters relating to the provision of on-line health care in the independent sector. Evidence was also heard from a number of general practitioners who provide prescriptions for prescription only medications on-line. This evidence identified the three main concerns listed below. 1. There is no single database that allows a prescribing clinician to identify what prescription only medication has already been prescribed to any particular patient. Because there is no central record, in order for the prescribing clinician to identify previous/current prescriptions, they need to personally contact every other prescribing clinician or clinicians. Before being able to do this they would need to obtain the patients express permission. The evidence heard clearly demonstrated that this system was totally ineffective in Debbie's case, especially so in relation to the supplies of prescription only medication from on-line. It was identified that in relation to the prescription of opiate based drugs on-line that the NHS Business Authority already collates that data for NHS prescribers. However, this information is currently used for statistical purposes only and does not include any prescriptions from third party providers. 2. Evidence was heard from both the CQC and CQC registered on-line pharmacists of the changes that have been made to the way in which the prescription of opiate based medication (including codeine) is now conducted. CQC registered pharmacies should now not supply opiate based medications unless the patient provides permission for them to contact their registered GP. However, those suppliers who do not want to adhere to this requirement are simply changing their business model (primarily by only using prescribing doctors based overseas) and are relinquishing their CQC Regulated status. These prescribers are therefore still able to provide on-line prescription services (including opiate based medication) in the UK but now fall outside the CQC regulation regime. Clearly this is an area of concern as it will continue to allow patients to access uncoordinated quantities of prescription only medication from unregulated on-line suppliers.

	3. New guidance from the General Pharmaceutical Council was issued in April 2019 and this includes specific advice regarding on-line prescriptions. This is clearly welcome, however some witnesses highlighted that the guidance is advisory and not mandatory. As such there was some uncertainty as to what sanctions would be available against any supplying pharmacist who chose not to adhere to the new guidance?
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you or 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 13th January 2020 I, the Senior Coroner, may extend the period if I consider it reasonable to do so. 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 and to the following Interested Persons (see separate addendum for the complete list of Interested Persons). I am 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 Senior Coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**18th November 2019** N. Parsley **Nigel Parsley**