REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Department for Health and Social Care** **Ministerial Correspondence and Public** **Enquiries Unit** **Department of Health and Social Care** **39 Victoria Street** **London** **SW1H 0EU**
1	**CORONER** I am Stephen Simblet KC, assistant coroner, for the coroner area of Essex
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 29th September 2022 I commenced an investigation into the death of **Frederick William LE GRICE, aged** 80. The investigation concluded at the end of the inquest on 29th September 2023. The conclusion of the inquest was natural causes, and that the medical causes of death were 1a) **Pneumonia 1b) Interstitial Lung Disease 1c) Nitrofurantoin Toxicity II Left Ventricular Systolic Dysfunction**
4	**CIRCUMSTANCES OF THE DEATH** Frederick Le Grice suffered with prostate problems, which as is the case, and did in this case, lead to urinary tract infections. There are two particular antibiotics used to treat such infections, Nitrofurantoin and Trimethoprim, along with urology support in hospital. The deceased had still continued to get UTIs when on trimethoprim, so his general practitioner prescribed nitrofurantoin. That drug carries with it a known, but rare, risk of lung damage. After using Nitrofurantoin for a number of years, the deceased began to suffer with coughing and breathlessness. He was referred for specialist respiratory advice and some time later, the respiratory consultant advised that he had interstitial lung disease, and the likely cause of the problems was the Nitrofurantoin, and that this should be discontinued, which it was. The deceased died two years later from pneumonia, with the interstitial lung disease and the nitrofurantoin toxicity contributing.
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** are as follows. – [BRIEF SUMMARY OF MATTERS OF CONCERN]

	(1) There is a known, albeit rare side effect of Nitrofurantoin, of it causing lung damage. Nevertheless, neither the deceased himself, nor the clinicians involved in the deceased's urinary care, who due to its specialism also have a prescribing function, were aware of the risk of lung damage from Nitrofurantoin. (2) It is not very clear in the guidance to general practitioners or patients generally, that the patient and the treating clinicians should be particularly alert to any signs of coughing or breathlessness, and that if they are present, it may well suggest that Nitrofurantoin is causing damage to the patient's lungs. Such damage is likely to be irreversible. (3) I am concerned as to the effectiveness of the guidance and information available: (i) to general practitioners and prescribers treating those using urinary catheters and/ or suffering from urinary tract infections; (ii) clinical staff in urology care; (iii) patients themselves Of the danger that Nitrofurantoin might cause lung damage, and (a) the need for all to be particularly vigilant as to symptoms and signs such as coughing or difficulty in breathing, and the desirability of their breathing and respiratory abilities being regularly monitored when a patient is using Nitrofurantoin (b) produces leaflets/ information resources to that effect.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you [AND/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 []27th November 2023. 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 and to the following Interested Persons [redacted] [and to the LOCAL SAFEGUARDING BOARD (where the deceased was under 18)]. I have also sent it to [redacted] 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.
9	**29th September 2023**