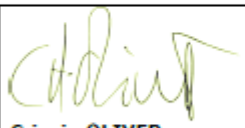
Regulation 28: REPORT TO PREVENT FUTURE DEATHS

NOTE: This form is to be used **after** an inquest.

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1 Claypath And University Medical Group** **2 [redacted] Chief Executive, Royal Pharmaceutical Society** **3 [redacted] Chief Executive, National Institute For Heath Care Excellence**
1	**CORONER** I am Crispin OLIVER, Assistant Coroner for the coroner area of County Durham and Darlington
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 02 December 2021 I commenced an investigation into the death of Jane Elizabeth ALLISON aged 84. The investigation concluded at the end of the inquest on 01 March 2022. The conclusion of the inquest was that: Died at University of North Durham on 20th November 2021. She had been admitted to the hospital on 11th November. She had been started on the nitrofurantoin for a UTI on 28th October. This is a conventional medication. She had a total course of 10 days. There were telephone consultations with her GP on 5th and 10th November. She suffered side effects of the medication but respiratory problems were not reported or noted. On 11th November she was discovered to be suffering from catastrophic pulmonary damage.
4	**CIRCUMSTANCES OF THE DEATH** Jane passed away in hospital after being admitted on 11th November 2021 with severe type 1 respiratory failure.
5	**CORONER'S CONCERNS** During the course of the investigation my inquiries 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) The Cause of Death provided by post mortem autopsy was 1)a) Acute Pulmonary Damage b) Administration of Nitrofurantoin for Urinary Tract Infection. The conclusion of the Inquest was a narrative one, that she "died from the effects of prescribed medication". The following, I acknowledge: that Nitrofurantoin is a well established medication with a long history of proven efficacy; deaths associated arising from side effects are very rare; the drug BNF content published by NICE does include in the listed side effects pulmonary and respiratory issues; likewise the BNF content does say that that in relation to monitoring of patient parameters "on longer-term therapy ...monitor for pulmonary symptoms, especially in the elderly (discontinue if deterioration in lung function)". All this said, Jane was aged

	84. She was he was extremely fit and active for her age, but this has the effect of heightening my concerns, as does that fact that she had no relevant co-morbidities. Also the course of treatment of the drug in this instance was not long, being 10 days in total, after which she died as a consequence of catastrophic pulmonary failure. Her GP, while reporting that Jane never informed her of any breathing difficulties when she consulted with her, also said that she had simply been following BNF content advice on this medication. In effect, my concern is that the BNF content had not advised to be alert to the danger of sudden pulmonary deterioration in an elderly patient, and certainly not one who was fit and active, and not in the context of the duration of a prescribing, dispensing and administration period of only 10 days. Effectively, the BNF content did not cover the eventuality of this case in that it was deficient in providing advice as to monitoring and being alert for pulmonary failure. For the avoidance of doubt, I am including the GP medical centre as a recipient of my concerns as clinicians there may concur with them, albeit the extent of their reaction to this death has been limited to peer group review and advice limited to within that medical practice.
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 May 02, 2022. 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] I have also sent it to **Dr [redacted] Claypath And University Medical Group** who may find it useful or of interest. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any person who I believe may find it useful or of interest. 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	**Dated: 07/03/2022**



Crispin OLIVER
Assistant Coroner for
County Durham and Darlington