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:** - **Greater Manchester Medicines Management Group**
1	**CORONER** I am Elizabeth WHEELER, Assistant Coroner for the coroner area of Cheshire
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 04 March 2025 I commenced an investigation into the death of Alan CRABTREE aged 84. The investigation concluded at the end of the inquest on 26 January 2026. The conclusion of the inquest was that: Misadventure
4	**CIRCUMSTANCES OF THE DEATH** <u>My findings in Box 3 were:</u> On 3 February 2025 Mr Crabtree was prescribed methotrexate for ongoing rheumatoid issues. This was clinically indicated and the risks were explained. He developed idiosyncratic side effects to the methotrexate – namely, the rapid development of pancytopenia. He was admitted to Macclesfield Hospital on 18 February 2025 as a result of the symptoms of methotrexate induced pancytopenia and was treated for these. Despite treatment, due to his compromised immune system, he developed pneumonia and died on 1 March 2025 <u>Issues</u> The issues explored during this inquest related to the dosage range of Methotrexate for treatment of adult patients with rheumatological conditions and the guidance provided to patients as to what actions they should take if they develop signs of Methotrexate toxicity such as sore throat, mouth ulcers and difficulty swallowing; specifically who should they seek advice from in those circumstances. As part of the exploration of these issues, evidence was heard in respect of the available local and national guidelines and protocols to assist clinicians in these particular areas including the Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults ("The Shared Care Protocol") which was produced by the GMMMG dated 14 September 2017 which was due for renewal on 19 October 2020. According to the evidence at Inquest, this guideline has not been updated since 2017 and remains in place today. There are two aspects of the Shared Care Protocol that were revealed as causing potential

	issues in the course of the evidence at the inquest: 1. During the inquest, evidence was heard that the dose range referred to within the Shared Care Protocol of 5-15mg for an initial dose, titrated up to maintenance dose of 20-25mg does not reflect current practice; the evidence was that in practice the low dose of 5mg is not routinely prescribed, and is rarely used in clinical practice in rheumatology as it would be considered sub therapeutic. Furthermore, the Shared Care Protocol does not provide any guidance in respect of when doses should be adjusted and factors to take into account to assist clinical decision making when advising on the appropriate starting dose. The suggested dose titration also requires review to ensure patients reach target dose in a timely manner. The guidelines do not appeared to have recently been reviewed to ensure that they in line with current accepted practice and other national guidance available. 2. In Mr Crabtree's case, the family sought advice from a Community Pharmacist when he displayed symptoms of a sore throat, mouth ulcers and difficulty swallowing and treatment was provided as part of the Pharmacy First Scheme. The concern raised during the inquest was the potentially ambiguous use of term "medical attention" in section 14 which reads: *"Patients should be advised to seek medical attention for the following:* - *Patient should report all symptoms and signs suggestive of blood disorders (eg sore throat, bruising and mouth ulcers)* - *Patients should report all symptoms and signs suggestive of liver toxicity (eg nausea, vomiting, abdominal discomfort, dark urine and jaundice)* - *Patient should report any upper abdominal pain as this is an indicator of development of pancreatis* " The Shared Care Protocol was drafted prior to the introduction of the Pharmacy First Scheme and the expanded role of Community Pharmacists which patients may consider could form part of "medical attention". This is also not in line with the Arthritis UK Patient Information Leaflet which states patients should inform their "doctor or nurse specialist" if they have signs of a sore throat and/or sores in the mouth. The Shared Care Protocol is not clear to patients who they should be seeking advice from to ensure they obtain the appropriate care and treatment and as currently drafted does not reference to the expectations surrounding Community Pharmacists under the Pharmacy First Scheme.
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) 1. The dose regime referred to in the "Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults" does not reflect current practice and the initial dose recommended is a sub-therapeutic dose. 2. The "Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults" was produced in September 2017. Since then, the "Pharmacy First" scheme has come into effect. The guidance therefore does not reflect the changes in the relevant responsibilities between secondary care, GPs and community pharmacists leading to ambiguity as to what type of healthcare professional a patient should consult and potentially fatal delay in ceasing methotrexate or commencing treatment for toxicity for the same.
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 April 17, 2026. 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 I have also sent it to 1. Mr Crabtree's family 2. East Cheshire NHS FT 3. Stockport NHS FT 4. [redacted] 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: 20/02/2026** [redacted] **Elizabeth WHEELER** **Assistant Coroner for** **Cheshire**