

November 3, 2016

Mabel E. Echols
Records Management Specialist
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 10202
725 17th Street, NW
Washington, DC 20503

RE: SAMHSA – 4162-20 Rule

Dear Ms. Echols:

Consistent with established guidelines, I am writing to request a meeting with OMB/OIRA staff to discuss the impact of the final rule for SAMHSA- 4162-20: Confidentiality of Substance Use Disorder Patient Records.

The modification of the federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), is a priority for the Academy of Managed Care Pharmacy (AMCP). AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP has been working with a coalition of 28 health care stakeholders created by the Association for Behavioral Health and Wellness. The coalition, called the Partnership to Amend 42 CFR Part 2 (Partnership), is committed to aligning Part 2 with HIPAA to allow appropriate access to patient information that is essential for providing comprehensive patient care. We appreciate the Administration's efforts to modernize Part 2, as we share the same goal of protecting the confidentiality of patients while improving access to advances in the delivery of health care services.

Part 2 reform is particularly important as we work to address the nation's opioid crisis. The regulations are outdated and are not compatible with the way health care is delivered currently. Without access to a patient's complete medical record, including addiction records, providers and organizations are limited in their ability to care for those patients and may, for example, unknowingly prescribe, administer, or recommend an opioid to an individual being treated for addiction.

AMCP is the only pharmacy organization represented in the Partnership. AMCP members are involved in managing the selection of opioids and medication assisted treatment through population health management. AMCP members also develop, implement, and administer medication therapy management

Pharmacists, as medication experts, are integral members of health care provider teams who evaluate whether a patient is at risk or who is currently misusing or abusing opioids and whether a patient could be an appropriate candidate for medication assisted therapy. Access to a patient's complete medical record is critical to patient treatment, safety, and recovery. For example, S. 2866 and H.R. 5142, "Jessie's Law" seeks to provide for sharing of information concerning an individual's substance abuse treatment. "Jessie", after battling opioid addiction for years, was a recovering addict. She underwent surgery for a running related injury. The discharging doctor did not have access to her addiction treatment records and prescribed oxycodone. She died of an overdose.

Of equal concern for patient treatment, safety and recovery, is the multitude of unintended consequences of drug to drug interactions, adverse drug reactions, and even death. Opioids obtained legally, such as those containing oxycodone, and those obtained illegally, such as heroin, may have significant side effects when used with other legally prescribed medications. If a person with an addiction has taken an opioid either legally or illegally and then receives an additional dose of another opioid, an individual may either experience impairment in their ability to breathe, known as respiratory depression, coma, or even death. Opioids also interact negatively with other controlled substances or those not scheduled by the Drug Enforcement Administration. Pharmacists, working in collaboration with other members of the health care team, help to identify and resolve these issues potentially reducing overdose and death in many patients. However, medical interventions by pharmacists and other health care professionals cannot occur without access to full medical records.

Given the issues described above, the provisions of the final rule are critical to allow health care providers to receive access to these medical records for those individuals receiving treatment for addiction or those who have received treatment for addiction. AMCP would like the opportunity to review the final rule with you and your staff. Please contact me at scantrell@amcp.org or 703-683-8416 to schedule a meeting with AMCP and other members of the Partnership.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a horizontal line extending from the end.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer