

## **Justification Statement for Non-substantive Change**

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is requesting a non-substantive revision of the currently approved collection for OMB No. 0945-0010 to append two forms without changing any collection requirements or estimated burdens. The current information collection request (ICR) was approved on March 8, 2024, in connection with the publication of a final rule modifying 42 CFR part 2, Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 FR 12472 (February 16, 2024) (“2024 Part 2 Final Rule”). The burdens for completing the forms at issue were approved with that ICR, taking into consideration public comments received; however, the forms for collecting the information were not appended to the ICR package.

The purpose of the first form, 42 CFR Part 2 Breach Portal Required Information, is to provide a simplified procedure for Part 2 programs (or, where relevant, qualified service organizations acting on the programs’ behalf) to report breaches of Part 2 records to the Secretary of HHS (“Secretary”) as required under 42 U.S.C. 290dd-2(j) and 42 CFR 2.16(b). The 45 CFR Part 2 Breach Portal Required Information form will be available through the OCR online breach portal.

The purpose of the second form, Investigative Agency Annual Report to the Secretary, is to provide a simplified procedure for an investigative agency subject to Part 2 to report annually to the Secretary about the investigative agency’s use of the Part 2 safe harbor to satisfy the reporting requirements at 42 CFR 2.68. The Part 2 safe harbor limits liability for certain violations of Part 2 by an investigative agency that unknowingly receives Part 2 records before obtaining a required court order, provided that the investigative agency meets certain prerequisites. The Investigative Agency Annual Report to the Secretary form will be available on the HHS OCR Investigative Agency online reporting portal.