

INVESTIGATIVE AGENCY ANNUAL REPORT TO THE SECRETARY

The regulation that protects the “Confidentiality of Substance Use Disorder (SUD) Patient Records,” 42 CFR part 2 (“Part 2”), requires an investigative agency as defined at 42 CFR 2.11 (“you”) to report annually to the Secretary about the agency’s use of the Part 2 “safe harbor.” The safe harbor limits liability for certain violations of Part 2 by investigative agencies that unknowingly receive Part 2 records before obtaining a required court order. You must submit the report to the Secretary no later than 60 days after the end of each calendar year, to the extent applicable and practicable, concerning actions taken during the previous calendar year. (See 42 CFR 2.3(b) and 42 CFR 2.68.)

This report is required only if you used the safe harbor during the last calendar year.

Do not provide any patient identifying information from Part 2 records with this report.

Reporting Agency Information

Name of Investigative Agency:

Name and Title of Agency Contact:_____

Address:_____

Phone:_____ Email:_____

Legal Basis of Investigative Agency’s Jurisdiction Over the Activities of a Part 2 Program or Other Person Holding Part 2 Records (or Over Employees or Agents of a Program or Person):

Dates Covered by this Report: MM/DD/YY_____ through MM/DD/YY_____

Required Information on Retroactive Applications for Part 2 Court Orders

A. Applications to obtain Part 2 patient records to investigate or prosecute a Part 2 program or person holding Part 2 records (see 42 CFR 2.66):

1. In the last calendar year, how many applications did you file for a court order pursuant to 42 CFR 2.66(a)(3)(ii) for Part 2 patient records after you unknowingly obtained the records or discovered them in your possession?

2. In the last calendar year, how many of those applications were denied because the court found violations of Part 2?

3. How many times in the last calendar year did you return Part 2 records to the Part 2 program or person who held the Part 2 records or destroy the records after you unknowingly received the records without a court order?

B. Applications to obtain Part 2 patient records through placement of an undercover agent or informant within a Part 2 program (see 42 CFR 2.67):

1. In the last calendar year, how many applications did you file for a court order pursuant to 42 CFR 2.67(c)(4) to authorize the continued placement of an undercover agent or informant within a Part 2 program after you discovered that their placement was unknowingly within a Part 2 program?

2. In the last calendar year, how many of those applications were denied because the court found violations of Part 2?

3. How many times in the last calendar year did you return Part 2 records to the Part 2 program or person who held the Part 2 records or destroy the records after you unknowingly received the records without a court order?

ATTESTATION Information Screen

Please complete the Attestation form.

Under the Freedom of Information Act (5 U.S.C. §552) and HHS regulations at 45 CFR Part 5, OCR may be required to release information provided in your report.

OCR will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

I attest, to the best of my knowledge, that the above information is accurate.

* Name: Date: [system generated]