

Substance Abuse and Mental Health Services Administration (SAMHSA)

Confidentiality of Substance Use Disorder (SUD) Patient Records, 42 CFR Part 2, Final Rule

Guidance for State Health Data Organizations

The Department of Health and Human Services (HHS) issued the final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2. The regulations became effective as of March 21, 2017. This final rule makes changes to better align with advances in the US health care delivery system while retaining important privacy protections.

States that maintain hospital discharge reporting systems¹ and/or All-Payer Claims Databases (APCDs)² are concerned about the impact these revised rules will have on their statewide reporting systems. In general, the 42 CFR Part 2 rule limits data shared about a substance use disorder (SUD) service by a Part 2 Provider as well as other lawful holders of data related to services rendered by Part 2 providers.

States are assessing the implications of 42 CFR Part 2 on their statewide reporting systems and are seeking guidance related to SUD data collection and access. The National Association of Health Data Organizations (NAHDO) and the University of New Hampshire as the APCD Council Learning Network, have developed this guidance for state health organizations. The objective of this guidance is to help state reporting systems maintain the completeness of data reporting in compliance to the final rule's provisions.

Summary of the Major Provisions of 42CFR Part 2

There are 14 major provisions of 42 CFR Part 2 addressing reports of violations, revision of definitions, applicability, patient consent, security, disclosures, medical emergencies, research, and audit/evaluation. The two sections of the rule of most concern to the APCD system are the following:

- Subpart B---General Provisions: Sections 2.11 (definitions) and 2.12 Applicability.
- Subpart D: §2.2 (3) Disclosures without Patient Consent, Section 2.52 Research.

Subpart B: General Provisions---§2.12 Applicability

What data are subject to the rule?

Section 2.12 places restrictions on disclosures that would identify a patient as having or having had received SUD via information from a **federally-assisted Part 2 program** for the **purpose of treating a SUD**, making a diagnosis for the treatment, or making a referral for the treatment.

42 CFR part 2 regulations apply to “**a program that is federally assisted, and holds itself out as providing and provides, substance use disorder diagnosis, treatment, or referral for treatment**”.

- If a patient's SUD diagnosis, treatment, or referral for treatment is **not provided by a part 2 program**, that patient's record is not covered by the regulations in this part.

¹ Statewide hospital discharge data systems collect all-payer data (including self and uninsured) for all patients admitted to an acute care hospital in the state and contain a complete collection of demographic, clinical and billing data for each inpatient, Emergency Department, and Ambulatory Surgery admission.

² APCDs are large-scale databases that systematically collect health care claims data from public and private payers (insurance carriers, third-party administrators, pharmacy benefit managers, dental benefit administrators, state Medicaid agencies, and CMS). Statewide APCDs are usually created by a state mandate; in states without a legislative mandate, data may be reported to the APCD voluntarily. APCDs generally include data derived from medical claims, pharmacy claims, eligibility files, provider (physician and health care facilities) files, and dental claims.

NOTE: SUD services are frequently provided in settings that are not Part 2 providers; data

HINT: Some lawful holders / payers may receive a notice of non-disclosure or a part 2 flag with the provider claim.

- The limits in data sharing apply to Part 2 providers, as well as other lawful holders of data related to services rendered by Part 2 providers. It is the provider itself that is responsible for designating its status as a Part 2 provider. Lawful holders include third-party payers of claims from Part 2 Providers for SUD services.

One challenge with the rule is that there is no universal identification system to isolate Part 2 providers in claims data feeds. Part 2 providers are responsible for identifying themselves as Part 2 providers, and there is no mechanism from SAMHSA or other federal agencies to identify them in claims.

SAMHSA does conduct a Part 2 provider survey and posts Substance Abuse Facilities Data (NSSTATS) which summarizes statistics about patient SUD utilization and Part 2 provider profiles on its website: <https://www.samhsa.gov/data/substance-abuse-facilities-data-nssats/reports>. The latest year available is 2010, but it may be one tool to help states use to make assessments as to the scope of potentially redacted SUD claims.

For Hospital Discharge Data Systems (HDDS)

Because HDDS data are collected from acute care hospitals licensed in a state, the data would generally not fall within the Part 2 restrictions. While a hospital provides SUD services, acute care hospitals (including the emergency room) may not designate themselves as Part 2 providers, because their primary function is not in the delivery of SUD diagnosis and treatment services. A designated unit in a hospital or a specialty hospital may hold itself out as a Part 2 provider, with staff providing SUD diagnosis and treatment as a primary function, but acute care hospitals in general would not be impacted by the rule.

The comments within the final rule provide an example:

*The regulations **DO NOT APPLY** to emergency room personnel who refer a patient to the ICU for an overdose, unless the **primary** function of such personnel is the provision of substance use disorder diagnosis, treatment, or referral for treatment and they are identified as providing such services or the ER has promoted itself to the community as a provider of such services. (§2.12 (2)(e))*

For All-Payer Claims Databases:

The 42 CFR part 2 provisions cause more confusion in All-Payer Claims Databases (APCDs) than hospital discharge reporting systems, because the sources for APCD data are payers, which are “lawful holders” of part 2 SUD data. Claims for SUD services from a payer would likely include some Part 2 providers, as well as many providers who are not Part 2 providers. As such, payers are concerned about compliance to the rule’s disclosure provisions in their submissions of claims and administrative data to the state APCD agencies.

Recommendations

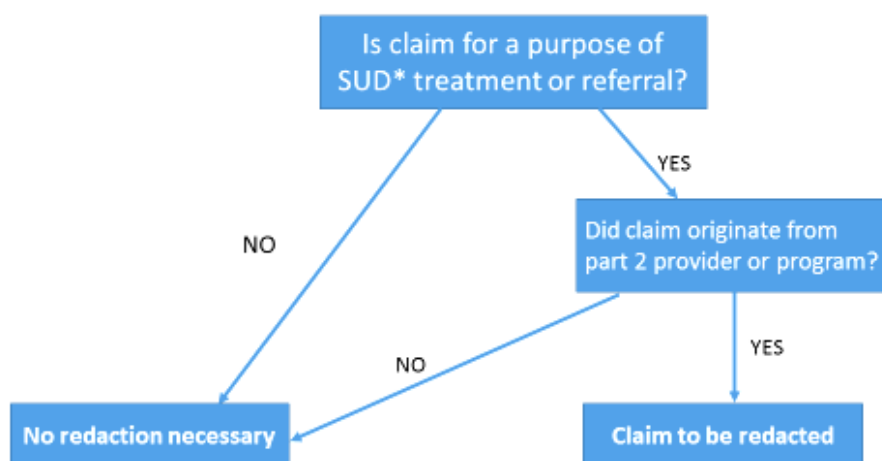
NAHDO is proposing two stages of response:

1. The first, shorter-term stage is to work with states and payers on protocols for data segmentation/redaction and options for de-identification of SUD claims. This redaction process can be reviewed and refined in collaboration with CMS, SAMHSA, payers, and states.
2. A longer term objective for states will be to identify mechanisms to receive SUD data through the allowances in section 2.52 of the 42CFR Part 2 rule.

Immediate Action: Stage I for State Response: Data Segmentation/Redaction Guidance for States

As states seek clarification for how 42 CFR Part 2 allows states to receive SUD data, states are addressing payers' desires to redact claims from data submission. Figure 1 provides a schematic of how data should be identified for redaction.

Redaction flow chart for claims with SUD Diagnosis and Procedure Codes



* SUD diagnosis means "any reference to an individual's substance use disorder or a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment".

However, due to the confusion around systematic identification of Part 2 providers in claims data, some lawful holders are erring on the side of suppressing all potential SUD claims from the APCD submission. This issue is compounded by the fact that there is no standard list of claims for filter/redaction, and payers and others are applying their own set of codes.

We propose states work with their data submitters to establish more uniformity around the scope and type of claims redacted prior to reporting to the state APCD. The following decision logic and tools may be helpful as state agencies work with their payers to apply a uniform redaction methodology.

NOTE: The redaction filter (or data segmentation of SUD claims) should only be applied at **the service or claim level** for those **related directly to SUD treatment**.

One tool states are adopting for redaction is the list of SUD codes that are applied by the Research Data Assistance Center (ResDAC) to Medicaid and Medicare research extracts, based on guidance from CMS.

These codes may be more inclusive than needed, but they provide a starting point for uniform redaction of SUD claims by carriers. Preliminary redaction statistics from one state using the CMS filter are consistent with the following redaction percentages from ResDAC for Medicare and Medicaid research extracts below.

Medicare – RESDAC analysis

Year	Claim Type	# Claims Suppressed	Total Claims	% Claims Suppressed	# Beneficiaries w/ Suppressed Claims *	Total Beneficiaries in Claims	% Beneficiaries w/ Suppressed Claims *	Medicare Payment (CLM_PMT_AMT) Suppressed Claims	Total Medicare Payment (CLM_PMT_AMT) in Claims
2013	HHA	45,668	6,905,823	0.66%	33,153	3,520,786	0.94%	104,524,486	18,178,400,969
	Hospice	5,618	4,253,743	0.13%	2,199	1,320,481	0.17%	19,677,441	15,122,668,648
	Inpatient	790,936	11,639,009	6.80%	515,787	6,811,960	7.57%	7,787,306,989	125,710,457,158
	Outpatient	1,133,258	161,427,011	0.70%	486,374	25,395,897	1.92%	477,731,285	57,237,878,481
	SNF	61,771	5,371,033	1.15%	29,803	1,938,541	1.54%	335,309,961	28,278,263,118
	Part A	2,037,251	189,596,619	1.07%	870,416	27,035,605	3.22%	8,724,550,162	244,527,668,374
	B-Carrier	4,396,703	893,325,107	0.49%	931,487	35,454,223	2.63%	418,815,290	89,761,228,438
	DME	5,957	68,643,147	0.01%	1,512	10,679,415	0.01%	1,184,195	8,691,488,513
	Part B	4,402,660	961,968,254	0.46%	932,066	35,643,813	2.61%	419,999,485	98,452,716,951
	Total	6,439,911	1,151,564,873	0.56%	1,331,397	36,414,803	3.66%	9,144,549,647	342,980,385,325

*Only the claims that contain the SUD codes are removed; not the beneficiary and all claims associated with that beneficiary

Medicaid – RESDAC analysis

Year	Claim Type	# Claims Suppressed	Total Claims	% Claims Suppressed	# Beneficiaries w/ Suppressed Claims *	Total Beneficiaries in Claims	% Beneficiaries w/ Suppressed Claims *	Medicaid Payment (MDCD_PYMT_AMT) Suppressed Claims	Total Medicaid Payment (MDCD_PYMT_AMT) in Claims
2010	Inpatient	773,353	9,378,620	8.25%	417,977	6,106,602	6.84%	3,040,765,005	35,166,806,936
	Long-Term Care	225,235	33,319,656	0.68%	38,945	1,648,083	2.36%	522,839,791	62,508,895,726
	Other Services	37,376,167	2,520,159,210	1.48%	1,415,671	62,063,859	2.28%	1,706,728,920	213,731,343,805
	Total	38,374,755	2,562,857,486	1.50%	1,628,983	62,381,748	2.61%	5,270,333,716	311,407,046,467

*Only the claims that contain the SUD codes are removed; not the beneficiary and all claims associated with that beneficiary

HINT: Pay attention to the rate of suppressed claims. High variability may be due to variation in redaction codes and methods. It will be important to work closely with carriers/data submitters on redaction methods.

Over the next year, we will work with SAMHSA, CMS, and states to refine the list of SUD redaction codes and the protocol for applying the codes consistently. The full table of codes applied for claims redaction is available at the ResDAC website at <https://www.resdac.org/resconnect/articles/203>. NAHDO will alert states when an updated filter becomes available

In addition, a method for systematically identifying Part 2 providers such that claims redaction can be limited to just those providers will be an area of focus.

Longer-term Action, Stage II for State Action:

Subpart D---Disclosures without Patient Consent, Section 2.52 Research

Comments submitted to SAMHSA about the final rule asked about allowances for disclosure of data to state data agencies. While there is not a part of the rule that explicitly addresses state agencies, a comment in the final rule states:

Regarding the specific scenario raised by commenters, SAMHSA wishes to clarify that MPCDs and other data intermediaries are permitted to obtain part 2 data under the research exception provided in § 2.52, provided that the conditions of the research exception are met. Furthermore, an MPCD or data intermediary that obtains part 2 data in this fashion would be considered a “lawful holder” under these final regulations and would therefore be permitted to redisclose part 2 data for research purposes, subject to the other conditions imposed under § 2.52. The final rule edits the language under paragraph 2.52(a) to clarify that the regulations do not prohibit such a disclosure.

NAHDO, in its work with the APCD Council, will work with states and SAMHSA on solutions for accessing SUD data for state policy purposes under the provisions outlined in section 2.52 research.

Conclusion

Resolving reporting issues related to SUD services is critical to states at a time in which opioids and opioid use is a priority public health issue in almost every state. States are seeking data to make informed policy decisions to address this issue and one of the important sources of data are APCDs. However, as important as opioid data are to states, the comprehensive reporting of other data collected by APCDs are also critically important to understand the health of the covered population, health system performance, price and utilization variation, and chronic disease costs and prevalence. Therefore, this guidance seeks to inform states on an approach to redact SUD claims in the short term, while considering means to allow states to receive SUD claims in the long-term.