



April 5, 2016

The Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, Maryland 20857

Re: Proposed Rulemaking on the Confidentiality of Substance Use Disorder Patient Records

To Whom It May Concern:

AcademyHealth, as the nonpartisan, professional home to more than 4,500 health services researchers, policy analysts, and practitioners, welcomes the opportunity to respond to the Notice of Proposed Rulemaking on the Confidentiality of Substance Use Disorder Patient Records (SAMHSA 4162–20).

Good research requires good data. SAMHSA’s predecessor agency recognized as much when it first adopted rules in 1976 to govern disclosures of patient records pertaining to substance use disorders (SUD): “[I]t would be wholly inappropriate to use the rulemaking process to impose an absolute requirement of patient consent with respect to [research] activities.” 40 Fed. Reg. 20536-37 (1976).

AcademyHealth therefore applauds SAMHSA’s proposal to bring the rule governing SUD disclosures to researchers into the 21st century. The rule, now codified at 42 CFR §2.52, has remained largely unchanged since its adoption and was last amended in 1987. *See* 52 Fed. Reg. 21800. It is now seriously outdated and poses a needless impediment to critical research.¹

In particular, AcademyHealth believes that the agency has recognized the need for an appropriate balance between research and privacy with the proposed rule. Allowing lawful holders of SUD records to share those records with researchers will enable vital research into diseases that afflict some of this nation’s most vulnerable populations. At the same time, adherence to the Common Rule’s stringent constraints on human-subjects research will protect the privacy of such records.

AcademyHealth is pleased to offer the following suggestions for your consideration as you work to finalize this policy. We will first summarize those areas where we offer general support, and follow with specific issues for future consideration.

¹ *See* Austin Frakt & Nicholas Bagley, *Protection of Harm? Suppressing Substance-Use Data*, 372 NEW ENG. J. MED. 1879 (2015).

General Support for Changes Governing Research Disclosures of SUD Records

In late 2013, and for the first time, the Centers for Medicare and Medicaid Services (CMS) began withholding SUD records from certain Medicare and Medicaid data sets that the agency had long provided to health services researchers. The change in policy resulted from CMS's effort to adhere to the long-overlooked strictures of 42 CFR §2.52, which allows research disclosures from “program directors” but not from “third-party payers” like CMS.

The change was unannounced and caught the research community by surprise. Because most private insurers are unwilling to voluntarily share their data, Medicare and Medicaid data offer by far the most comprehensive and detailed snapshot of health claims in the United States. But withholding SUD records from those data sets—including, in particular, Medicare and Medicaid Research Identifiable Files—has seriously compromised their integrity. In 2013 and 2014, for example, CMS withheld more than 6% of all Medicare inpatient claims and more than 8% of Medicaid inpatient claims.

The data-scrubbing is a tremendous problem for research into substance use disorders. Improving the lives of individuals who struggle with medical illnesses depends on solid research into quality of care and outcomes. Patients with substance use disorders should have the same opportunities as other patients to benefit from such research. Indeed, SAMHSA's goal is “to support new models of integrated health care which, among other things, improve patient safety while maintaining or strengthening privacy protections for individuals seeking treatment for substance use disorders.” *See* 81 Fed. Reg. 6990 (2016). Supporting those new models requires research to study their effects on patient health, and it would disproportionately harm those afflicted with substance use disorders to deprive them of the opportunity to benefit from that scrutiny.

The problem, however, extends well beyond research into substance use disorders. To conform to 42 CFR §2.52, CMS has withheld records that include substance use disorders as a secondary diagnosis. Many of the withheld records thus pertain to diagnoses that are unrelated to substance use disorders.

As a result, the data withholding will hamper research into patient populations with conditions that are more common among those who suffer from substance use disorders. A recent study, for example, used unscrubbed Medicaid data to examine readmission rates for patients diagnosed with schizophrenia.² For those patients who were hospitalized at least once, 51% had a co-occurring substance use disorder. They were much more likely than those who did not to be readmitted to the hospital within 30 days. This sort of vital research—especially vital now that U.S. Department of Health and Human Services has made it a top priority to reduce readmission rates—would have been impossible without Medicaid data on substance use disorders.

In a similar vein, a research letter recently published in the *Journal of the American Medical Association* examined six diagnoses that are associated with substance use disorders: Hepatitis C,

² *See* Alisa B. Busch et al., *Thirty Day Hospital Readmission for Medicaid Enrollees with Schizophrenia*, 18 J. MENTAL HEALTH POL'Y AND ECON. 115 (2015).

cirrhosis, tobacco use, HIV, depression, and anxiety.³ For all the conditions, the researchers observed an immediate and sharp discontinuity in inpatient diagnoses between unscrubbed and scrubbed data sets. In unscrubbed data from 2006, for example, about 2,076 Medicaid beneficiaries out of every 100,000 were diagnosed with HIV. In the scrubbed 2007 data, that figure plummets to 1,254. The researchers observed no dissimilar discontinuity for diseases that are not associated with substance use disorders (e.g., Type II diabetes), strongly suggesting that the data suppression, and not something else, is responsible. As they conclude:

“Underestimation of diagnoses has the potential to bias health services research studies and epidemiological analyses for which affected conditions are outcomes or confounders. In studies of health care utilization, the number of missing claims may vary in a nonrandom fashion between groups defined by demographics, disease, or locality. Comparisons between groups may lead to spurious conclusions—a hospital that regularly admits substance abusers will have artificially low rates of readmission, giving a false appearance of better performance.”

Now is an especially inauspicious time to hamper research into substance use disorders. The Centers for Disease Control and Prevention has concluded that “[t]he United States is experiencing an epidemic of drug overdose (poisoning) deaths.”⁴ That epidemic, as Anne Case and Angus Deaton have vividly demonstrated, is taking an enormous toll on public health.⁵ But withholding SUD records has already frustrated researchers’ efforts to understand the full scope of the growing problem. It will also hamper researchers’ efforts to develop evidence-based guidelines to aid physicians seeking to slow the epidemic.

AcademyHealth therefore strongly supports SAMHSA’s proposal to allow “lawful holders” of SUD records to share those records with researchers, subject to appropriate protections. As we understand the proposal, the rule would restore to CMS the authority to include identifiable SUD records in Medicare and Medicaid data without patient consent. It would also allow private employers and private insurers to share SUD records with researchers on the same footing.

Like SAMHSA, AcademyHealth recognizes the importance of maintaining the confidentiality of SUD records. But experience suggests that research disclosures are compatible with the highest standards of patient privacy. For decades prior to the 2013 change in policy, researchers received SUD records from Medicare and Medicaid. Yet, to our knowledge, no research-related disclosure has ever compromised an individual’s privacy. That is in part a function of the extensive safeguards that have long been in place to protect SUD records. Researchers who work with large datasets of patient-identifiable information are already subject to the stringent requirements of HIPAA’s Privacy Rule, the Privacy Act, the terms of their data use agreements,

³ See Kathryn Rough et al., *Suppression of Substance Abuse Claims in Medicaid Data and Rates of Diagnoses for Non-Substance Abuse Conditions*, 315 J. AM. MED. ASS’N 1164 (2016).

⁴ See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000-2014*, 64 MORBIDITY AND MORTALITY WEEKLY REPORT 1378 (2016).

⁵ See Anne Case & Angus Deaton, *Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century*, 112 PROCEEDINGS OF THE NAT’L ACADEMY OF SCIENCES 15078 (2015).

and the Common Rule, including oversight from Institutional Review Boards that are keenly aware of the sensitivity of SUD records. Among other things, researchers must demonstrate a need for SUD records and agree to adhere to stringent conditions on their protection and disposal. Violation of those conditions is a criminal offense.

We therefore endorse SAMHSA's efforts to restore access to data that can enable much-needed research into substance use disorders and associated conditions. We also join other commenters in support of the proposed rule's efforts to reduce barriers to information-sharing within and across health systems. Those barriers discourage integrated health systems from adopting a unified system for electronic health records, which in turn contributes to the incomplete capture of structured clinical information. That information is essential for sound research into the costs and quality of clinical care.

Items for Clarification

1. Data Linkages

The proposed rule contains a provision on “data linkages,” which is the practice of linking several datasets together in order to get a full picture of the care that members of a given population receive. For example, a Medicaid beneficiary may receive care through the Veterans Health Administration. To get a full picture of that patient's course of treatment, researchers must link Medicaid datasets with datasets from the VA. Patient-identifying information is necessary to make the necessary linkages.

AcademyHealth believes that the proposed rule is best read to allow researchers to perform their own data linkages between datasets containing SUD records. But the rule is not as clear on this point as it might be. Specifically, the rule sets out guidelines for any researcher “[t]hat requests linkages to data sets from a federal data repository(-ies) holding patient identifying information.” According to language in the preamble, this provision would (1) allow a researcher to disclose patient-identifying information to a federal data repository (like CMS); (2) permit the federal data repository to link the patient-identifying information to data held by that repository; and (3) return the linked data file back to the researcher.

AcademyHealth supports this approach as an *option* for researchers who request data linkages from the federal government. Indeed, AcademyHealth believes that this option should be available for researchers who request data linkages from state agencies and private groups—provided, of course, that these entities have appropriate security procedures in place. A state's all-payer claims database (APCD), for example, may be willing and able to link a researcher's Medicaid data with claims data from private insurers. SAMHSA's rule should encourage, not frustrate, those sorts of data linkages, which will provide a more complete portrait of the care delivered to those suffering from substance use disorders.

But *requiring* data linkages to be conducted by the federal government—and only by the federal government—would impede the very research that SAMHSA intends to encourage. CMS is overtaxed, and we are not optimistic that it will be able to expeditiously, inexpensively, and

accurately do the complex work associated with linking data across disparate data sets. Delays could be interminable; the price could be excessive; and mistakes would be inevitable.

We therefore encourage SAMSHA to clarify that researchers remain free to perform data linkages, subject to proper protections for patient confidentiality, between datasets that contain SUD records. Again, we believe this is already the best way to understand the proposed rule, which does not purport to prohibit researchers from creating their own linkages.

2. Data Intermediaries

Over the past dozen years, roughly 18 states have created all-payer claims databases (APCDs). These new databases aim to collect a comprehensive dataset of utilization and cost of health care services within the state. These state-mandated submissions create a data system that is inclusive both of public and private payers, with sample sizes and diverse population representation that allow for much more robust analysis of important health care issues than public-payer data alone. The hope is that APCDs will become vital resources for state policymakers and health services researchers who wish to use the data to learn more about how to develop low-cost, high-quality health care.

At the same time, private groups that collect, compile, and share medical data have come to prominence. These private intermediaries support providers and health systems in their efforts to improve the quality of clinical care and foster population health. To that end, the intermediaries combine claims data (both public and private), medical record data (both paper and electronic), patient-generated data (e.g., experience surveys and reported outcomes), and provider-generated data (e.g. provider registries) to benchmark quality and cost performance, provide quality and cost performance information to providers, and assist providers in targeting quality improvement interventions. Allowing data intermediaries to link substance use data with these other data sources may bolster population health and research efforts.

Collectively, these public and private data intermediaries perform a critical function in the health care ecosystem. They enable researchers to avoid the substantial and often unmanageable burden of collecting records from dozens or hundreds of separate providers, while at the same time offering a more complete picture of the health care delivery system. These intermediaries have already proven valuable for research and will become even more valuable in the future.

Unfortunately, SAMHSA's proposed rule may preclude data intermediaries from collecting SUD data from payers or providers within the state. Although the proposed regulations do not define "lawful holder," the preamble says that a "lawful holder" is someone who receives identifiable data "as the result of a part 2-compliant patient consent ... or as a result of one of the limited exceptions to the consent requirements specified in the regulations and, therefore, is bound by 42 CFR Part 2."

The proposed rule does not specify whether APCDs and other data intermediaries can qualify as lawful holders. AcademyHealth is concerned, however, that the definition offered in the preamble suggests they may not qualify. Patients generally do not consent to sharing data on substance use disorders with APCDs or other entities. Nor do the proposed rules governing

disclosures for research purposes appear to enable payers and providers to share SUD records with these intermediaries.

Data intermediaries may therefore be ineligible to receive identifiable SUD records. If they cannot collect SUD records, they cannot share such records with responsible researchers. Indeed, AcademyHealth has learned that health plans have already begun withholding SUD records from APCDs in some states, rendering them useless for research into substance use disorders or into conditions that disproportionately afflict those with substance use disorders. The APCDs in Massachusetts, Vermont, and New Hampshire, for example, will be unable to offer insight into how to deal with the states' opioid epidemics.⁶

That result is especially anomalous given that, under SAMHSA's proposal, state Medicaid agencies are lawful holders of SUD records and may therefore share those records with qualified researchers. If SAMHSA believes that state Medicaid agencies can be trusted stewards of substance use-related claims, why not the APCDs that are authorized to operate in states, at least if they maintain high standards for the protection of sensitive data?

In AcademyHealth's judgment, SAMHSA should clarify in its final rule that data intermediaries that maintain adequate safeguards are eligible to collect patient-identifiable SUD records without patient consent under the provisions of 42 CFR Part 2 governing research. Further, SAMHSA should clarify that such intermediaries may disseminate SUD records to qualified researchers, subject to the safeguards governing the conduct of other lawful holders of such records.

Thank you for the opportunity to submit these comments. We look forward to working with you to finalize and implement the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Simpson". The signature is fluid and cursive, with a large initial "L" and "S".

Lisa Simpson, M.B., B.Ch., M.P.H., FAAP
President and CEO, AcademyHealth

⁶ The Supreme Court's recent decision in *Gobeille v. Liberty Mutual Insurance Company* will allow self-insured employers to decline to share information on health care prices with APCDs. To the extent self-insured employers decline to share their data, APCDs will no longer be comprehensive. But they will still remain useful repositories of data from Medicare, Medicaid, private insurers, and employers that do not self-insure. Stripping SUD records from the APCDs will skew their remaining data and make them worthless for research into substance use disorders and associated conditions.