

## Substance Abuse and Mental Health Services Administration Rule on Confidentiality of Substance Use Disorders Patient Records

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### Health Policy Research Subcommittee

One role of the SGIM's advocacy efforts in research and health policy involves closely following legislation and federal rules that impact SGIM researchers. In recent years, we have been following the Substance Abuse and Mental Health Services Administration (SAMHSA) rule about access to substance use data in Medicare and Medicaid files.

In 2013, the Centers for Medicare and Medicaid Services (CMS) began to withhold any claim with a substance use disorder diagnosis or related procedure code from Medicare or Medicaid research data sets in response to concerns about protection of patient privacy. This data suppression is estimated to affect about 4.5% of all inpatient Medicare claims and 8% of inpatient Medicaid claims, and it seriously impedes the ability of researchers to study care for millions of Americans with substance use disorders.<sup>1</sup> At a time when our country is facing a critical opioid crisis and attempting to improve care for individuals with mental illness and substance abuse, as well as hepatitis C and HIV/AIDS—which are associated with substance abuse—substantial concern has arisen regarding our ability to identify gaps in the actual care of these populations.

The original privacy regulations date back to 1975. These rules were written in a way that authorizes providers of care to disclose data on substance-use disorders for research purposes, but prohibits third party payers (including CMS) from doing so.<sup>1</sup> In 2013, SAMHSA required CMS to suppress substance use information to comply with the regulations.

This recommendation was surprising to many, especially as the law on which the original regulations were based stated that identifiable data on substance-use disorders “may be disclosed” even without patient consent “to qualified personnel for the purpose of conducting scientific research.” Since late 2013, Medicare and Medicaid claims data used for research have omitted any claim with a primary or secondary diagnosis code for substance use disorder.

In February 2016, responding to concerns about this change in policy, SAMHSA released a proposed rule for comment that would restore access to Medicare and Medicaid claims involving substance use disorder. The proposed rule would expand the definition of “providers” who may legally share these data with researchers to anyone who is a “lawful holder” of data, including third-party payers. This goes a long way toward addressing the problems, by restoring to CMS the authority to include identifiable substance use records in Medicare and Medicaid data and allowing private employers and insurers to do the same.

In April, members of the SGIM Health Policy Research Subcommittee (some of whom also participated in similar efforts by Academy Health) sent letters strongly supporting SAMHSA's proposed rule, while also making additional recommendations. Specifically, we commented on two aspects of the proposed rule that would benefit from more clarification. First, we shared concerns about the aspect that addressed data linking. Language of the proposed rule could be interpreted to suggest that *only* the federal government can imple-

ment linkages between datasets that contain substance abuse data. Our hope is that the intent of this part of the rule will enable both the federal government *and* other entities (with the proper data security) to create such linkages. It would be unnecessary, impractical, and costly for the federal government to do all data linkages. Many researchers have tremendous expertise with such linkage processes, and have been making these linkages safely and confidentially for years.

The second point involved data intermediaries. The proposed rule was somewhat unclear about what parties qualify as “lawful data holders.” There are a number of non-federal entities that are very important data intermediaries, including state entities that administer All-Payer Claims Datasets (APCDs) and private entities that hold and analyze data. Such non-federal entities are increasingly important sources of data for improving the quality and value of care provided to patients with substance abuse disorders. We believe that the regulation should clarify that non-federal entities could qualify as “lawful data holders.”

As this article goes to press, the final regulation has not been released. The SGIM Health Policy Research Subcommittee will continue to follow this issue closely with the hope that the rule will be revised to address these remaining concerns.

### References

1. Frakt A, Bagley, N. Protection or Harm? Suppressing Substance-Use Data. *N Engl J Med*. 2015; 372: 1879-1881.