

## **State Attorneys General**

### **A Communication from the Chief Legal Officers of the Following States and Territories:**

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Georgia \* Hawaii \* Indiana \* Kentucky \* Louisiana\* Maine  
Michigan \* Mississippi \* Missouri \* Montana \* Nebraska  
New Hampshire \* New Jersey \* New Mexico \* North Carolina  
North Dakota \* Ohio \* Oklahoma \* Rhode Island \* South Carolina  
South Dakota\* Tennessee \* Texas \* Vermont \* Virginia \* West Virginia  
Wisconsin \* Wyoming**

April 11, 2016

The Honorable Sylvia Mathews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Ave, S.W.  
Washington, DC 20201

Re: Confidentiality of Substance Use Disorder Patient Records, 81 Federal Register 6988  
(February 9, 2016) Comments to Proposed Rulemaking

Dear Secretary Burwell:

This letter is submitted as a public comment to the proposed Confidentiality of Substance Use Disorder Patient Records, 81 Federal Register 6988 (February 9, 2016) (Proposed Regulation), on behalf of the Attorneys General. We appreciate this opportunity to provide comments on the Proposed Regulation.<sup>1</sup> As the chief legal officers of our states, we are extraordinarily concerned with the epidemic of heroin use and prescription opioid abuse that has taken the lives and diminished the wellbeing of thousands of our citizens. We are also encouraged by the willingness of Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to consider revisions to 42 CFR Part 2 to help us fight the scourge of drug addiction that is destroying the fabric of our communities.

The Secretary of HHS is charged with implementing the confidentiality provisions of 42 U.S.C. § 290dd-2 by promulgating regulations such as 42 CFR Part 2, and the Secretary has the authority and the right to amend such regulations when appropriate.<sup>2</sup> That time has come.

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<sup>1</sup> *Confidentiality of Substance Use Disorder Patient Records*, 81 Fed. Reg. 6988 (proposed Feb. 9, 2016) (to be codified at 42 C.F.R. Part 2). <https://www.federalregister.gov/articles/2014/05/12/2014-10913/confidentiality-of-alcohol-and-drug-abuse-patient-records>.

<sup>2</sup> 42 U.S.C. § 290dd-2.

We recognize that the main purpose of 42 CFR Part 2 is to encourage patients with substance use disorders (SUDs) to seek treatment without fear of prosecution or discrimination, and we share SAMHSA's commitment to the privacy interests surrounding an individual's treatment for substance abuse. However, patient privacy must be balanced with (1) the need to ensure that individuals with SUDs receive comprehensive, safe, and efficacious treatment, and (2) the immediate need to reduce the diversion, misuse, and abuse of controlled prescription medications. With those goals in mind, we encourage HHS to revise the regulations to permit opioid treatment programs (OTPs) to submit dispensing data to state prescription drug monitoring programs (PDMPs).

Under the current 42 CFR Part 2 regulations, a patient must give explicit, written consent to permit the release of certain SUD treatment records, unless a particular exception applies.<sup>3</sup> The consent must identify to whom the records are released, and a period of time for which consent will be valid; re-disclosure is prohibited without additional patient consent.<sup>4</sup>

Currently, 42 CFR Part 2 applies to federally assisted drug abuse programs.<sup>5</sup> A "program" is defined as any individual or entity that is federally assisted and holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment.<sup>6</sup> A program is considered to be federally assisted if it is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States.<sup>7</sup> For-profit programs and private practitioners are not subject to these regulations unless the State licensing agency requires them to comply or the physician is subject to the regulations through his or her Drug Enforcement Administration (DEA) registration.<sup>8</sup> The regulation also does not apply to pharmacists because pharmacists do not fall under the definition of federally assisted drug abuse programs.<sup>9</sup>

PDMPs are statewide programs that collect patient-specific data on various controlled prescription medications and that enable prescribers, pharmacists, regulatory boards, and, in some states, law enforcement agencies, to access this information under state law. These programs are valuable tools to improve patient safety and health outcomes. PDMPs can aid the care of patients with chronic conditions and help identify persons engaged in high-risk behavior, such as doctor shopping and prescription forgery, indicating possible abuse of or dependence on controlled substances.<sup>10</sup>

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<sup>3</sup> 42 C.F.R. § 2.31, 2.33.

<sup>4</sup> 42 C.F.R. § 2.31, 2.32.

<sup>5</sup> 42 C.F.R. § 2.12.

<sup>6</sup> 42 C.F.R. § 2.11.

<sup>7</sup> 42 C.F.R. § 2.12.

<sup>8</sup> Susan Awad, *Confused by Confidentiality? A Primer on 42 CFR Part 2*, AM. SOC'Y FOR ADDICTION MED., (Aug. 15, 2013), <http://www.asam.org/magazine/read/article/2013/08/15/confused-by-confidentiality-a-primer-on-42-cfr-part-2>.

<sup>9</sup> See 42 C.F.R. § 2.11.

<sup>10</sup> G.C. Alexander, S Frattaroli, A.C. Gielen, eds, *The Prescription Opioid Epidemic: An Evidence-Based Approach*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH (Nov. 2015), <http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf>.

Yet, PDMPs are severely underutilized by prescribers, and regulations, such as 42 CFR Part 2, are a significant barrier for physicians to provide valuable data to PDMPs.

Currently, two kinds of prescription opioids are used to treat patients with opioid use disorders: methadone and buprenorphine. Methadone is dispensed only at OTPs. Methadone may not be prescribed, so patients are not able to obtain it from a pharmacy. All OTPs are required to obtain certification from SAMHSA, and, therefore, meet the regulatory definition of “federally assisted drug abuse program.”<sup>11</sup> As such, they are not allowed to submit dispensing information to PDMPs. As a result, PDMPs do not contain data regarding patients receiving methadone, even when the same patients are treated by other providers who do participate in the PDMPs. Physicians treating patients who are currently on methadone may prescribe medications that interact with methadone or, worse, that may lead to overdose and death.

On the other hand, buprenorphine is prescribed in an office-based treatment setting, and an individual prescribed buprenorphine is typically required to fill the prescription at a pharmacy. Since pharmacies are not regulated through 42 CFR Part 2, pharmacies may, and are sometimes required to, submit dispensing information to PDMPs. Therefore, PDMPs have access to dispensing data regarding buprenorphine.

An arbitrary and dangerous distinction is thus created whereby buprenorphine data is disclosed to PDMPs simply because it is dispensed by a pharmacy, but methadone data is not disclosed to PDMPs because it is dispensed in an OTP. This arbitrary distinction leads to inferior treatment for patients receiving methadone-assisted therapy compared with patients receiving buprenorphine-assisted treatment. Some individuals who intend to divert or abuse their medications actually seek treatment at OTPs because they know they have less of a chance of being caught by their doctors.

States have safeguards that would preserve the goals of 42 CFR Part 2 if OTPs are required to disclose methadone dispensing data. Although data is released to PDMPs, privacy protections ensure that patients may continue to seek treatment without fear of prosecution. The primary intended users of PDMP databases are health professionals, not law enforcement personnel. Those states that allow law enforcement access to the data impose restrictions limiting that access.<sup>12</sup> These states often require a court order, or, at the very least, some formal showing of a reasonable belief that unauthorized acquisition of controlled substances has occurred or is occurring.

We encourage you to exercise your rulemaking authority under 42 U.S.C. § 290dd-2 to revise the current regulations to require OTPs to submit dispensing data to PDMPs in accordance with state laws. This action will reduce the diversion, misuse, and abuse of opioids, and enable individuals with substance use disorders to receive comprehensive, safe, and more effective treatment while continuing to provide adequate privacy protections for individuals with substance use disorder. We are confident that this action will save lives.

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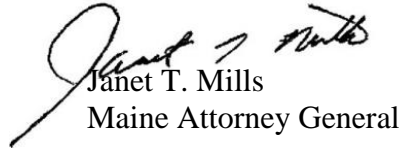
<sup>11</sup> *Certification of Opioid Treatment Programs (OTPs)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <http://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs> (last visited Dec. 22, 2015).

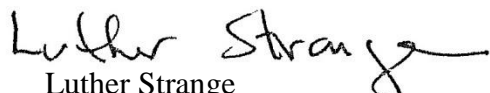
<sup>12</sup> *Types of Authorized Recipients – Law Enforcement Officials*, NAT’L ALLIANCE FOR MODEL STATE DRUG LAWS (Dec. 2014), <http://www.namsdl.org/library/BCEA5CFB-E29A-B561-3B62960EF453D9B3/>.


Thank you for your prompt consideration of this request. If you have any questions, please contact Attorneys General Mills or Olens or any of the signatories listed below. Thank you.

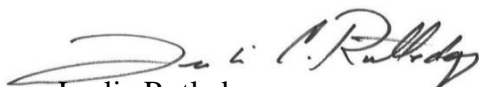
Sincerely,


  
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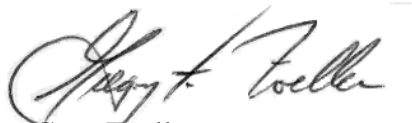
  
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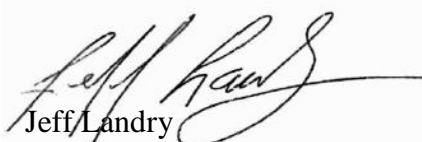
  
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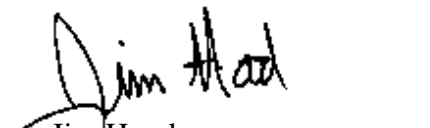
  
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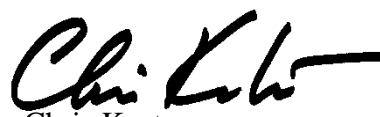
  
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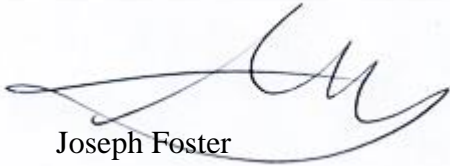
  
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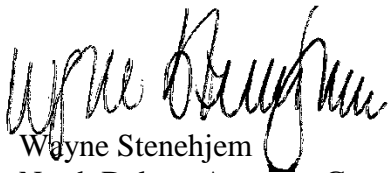
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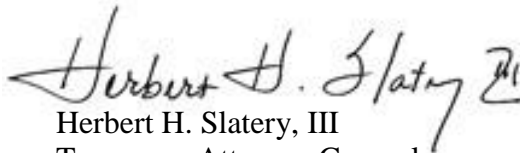
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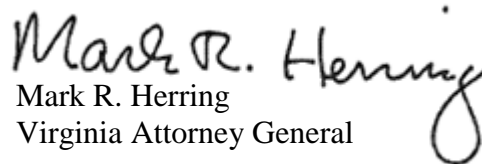
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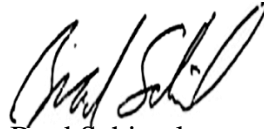
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