

Confidentiality Restrictions on Substance Abuse History

Question Presented

What legal duties does an employee of a prosecutor's office have with respect to keeping information confidential about a defendant's/diversion participant's substance abuse history? To whom may the prosecutor reveal information regarding that participant's substance abuse history, for what purposes, and what information can be revealed?

What ethical duties does an employee of a prosecutor's office have with respect to the above?

How does the newly-passed federal CARES Act affect any of these obligations, or more broadly, any prosecutor-led outreach to defendants/diversion participants with substance use disorders?

Short Answer/Research Points

Legal Duties

Substance abuse treatment programs must comply with both 42 C.F.R. § 2, known as Part 2, and the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. § 164. Where the laws conflict with each other or state law, a program should comply with the most restrictive law that gives greater protection to patient information or that gives greater control of their information to the patient. Since Part 2 gives greater privacy protection than HIPAA's privacy rule, this generally means that, prior to the CARES Act, programs should continue to follow Part 2's general rule to not disclose information unless they can obtain consent or point to an exception to that rule that specifically permits the disclosure. While no state law may authorize or compel any disclosure prohibited by Part 2's regulations, states may impose additional confidentiality protections. Thus, if a disclosure permitted under Part 2 is prohibited under state law, a program should follow state law. See 42 C.F.R. § 2.20.

However, the recent passing of the CARES Act suggests that Part 2 programs can disclose information for **treatment, payment and health care operations** in accordance to HIPAA's less stringent requirements as long as a patient gives initial written consent. The CARES Act's full impacts are not entirely clear until the Substance Abuse and Mental Health Services Administration (SAMHSA) incorporates changes into its Part 2 regulations. Unlike other provisions of the CARES Act, amendments related to Part 2 and HIPAA will not take effect until the Secretary of Health and Human Services consults with other federal agencies (including SAMHSA, a sub-division of the Department of Health and Human Services) to implement the amendments.

Covered entities under Part 2 are individuals or entities that are federally assisted and hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or referral for treatment. 42 C.F.R. § 2.11.

Under 42 C.F.R. § 2.12, an employee of a prosecutor's office that provides or refers individuals to substance abuse treatment cannot disclose participants' identities or records without participant consent. This includes information that:

- Would identify a participant as having or having had a substance use disorder (SUD), either directly, by reference to publicly available information, or through verification of such identification by another person, § 2.12(a)(1)(i);
- Is drug or alcohol abuse information obtained through any federally assisted drug abuse program after March 20, 1972, any federally assisted alcohol abuse program after May 13, 1972, or is maintained by a Part 2 program after either date as part of an ongoing treatment episode which extends past that date for the purpose of treating a SUD, making a diagnosis for that treatment, or making a referral for that treatment, § 2.12(a)(1)(ii).

However, the prosecutor may reveal participants' identities or records without participant consent in the following circumstances:

- Interchange of information in connection to the Department of Veteran Affairs provision under Title 38, U.S.C., § 2.12(c)(1)
- Interchange of information within the Armed Forces, § 2.12(c)(2)
- Communication within the program or between the program and an entity having direct administrative control over the program, § 2.12(c)(3)
- Qualified service organization agreements (QSOAs), § 2.12(c)(4)
 - A qualified service organization (QSO) is a person or organization that provides services to a [Part 2] program, and has entered into a written agreement with the program under which the QSO acknowledges that in dealing with any patient records from the programs, it is fully bound by these regulations and if necessary, will resist in judicial proceedings any efforts to obtain access to patient records, except as permitted by these regulations. § 2.11.
- Reporting a patient's crime on program premises or against program personnel, § 2.12(c)(5)
- Child abuse or neglect reports required by state law, § 2.12(c)(6)
- Medical emergencies, § 2.51
 - Patient-identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained. § 2.51(a).
 - Although courts have not explicitly defined or further clarified what constitutes a medical emergency, the Legal Action Center provides a helpful scenario: an unconscious patient arrived at the emergency department with symptoms of an overdose, was then treated by a specialty SUD overdose team that is a covered entity under Part 2, and then transferred to the ICU and attended by ICU staff. If the patient's ICU doctor, who is not part of a Part 2 program and does not work in the specialty SUD overdose team, wants to discuss the patient's status with the patient's family or close friend, the doctor is able to because Part 2 does not apply to the ICU



doctor's communications with the patient's family and HIPAA allows this disclosure. However, when communicating with the patient's family or close friend, the ICU doctor may not re-disclose information that the doctor received from the specialty SUD overdose team that identifies the patient as being diagnosed, treated or referred for SUD treatment, without first obtaining the patient's written consent. Although the § 2.51 medical exception allowed the Part-2 covered SUD overdose team to disclose information to the ICU doctor because the ICU doctor is medical personnel, and the patient was unconscious and unable to give prior consent,

§ 2.51 does not permit the re-disclosure of the information from the ICU doctor to the patient's family or friends without the written consent of the patient, because the patient's family or friends are not medical personnel (or functioning in their capacity as medical personnel, in this example). See Memorandum from the Legal Action Center on Privacy Rights of Patients Treated for Overdose in Emergency Departments to Hospital Executive Directors and Administrators, General Counsels, Chiefs of Emergency Medicine, Directors of Nursing – Emergency Services 8 (Mar. 16, 2018) (on file with author).

- According to the SAMHSA guidance on Part 2 disclosures, it is up to the health care provider or facility treating the emergency to determine the existence of a medical emergency, and which personnel are needed to address the medical emergency. See *Substance Abuse Confidentiality Regulations*, SAMHSA (Apr. 14, 2020), <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>. An example of a medical emergency under Part 2, in which prior consent is unobtainable, is if there is a situation that poses an immediate threat to the health of any individual and requires immediate medical intervention. *Id.*
- Of note, a bona fide medical emergency under § 2.51 is specific to the individual patient and not a blanket emergency, such as the current COVID-19 public health emergency. See *Disclosure of Substance Use Disorder Records During COVID-19*, WASH. ST. HOSP. ASS'N (Apr. 20, 2020), <https://www.wsha.org/articles/disclosure-of-substance-use-disorder-records-during-covid-19>. For example, a hospital treating a COVID-19 patient that believes past SUD treatment may be relevant to emergency care for that COVID-19 patient may access SUD information from a Part 2 entity under the § 2.51 exception.
- Immediately following disclosure, a Part 2 program should document specific information related to the medical emergency. §2.51(c).
 - Research requests, § 2.52
 - Qualified audit or evaluation of the program, § 2.53
 - Court orders authorizing disclosure and use of the patient records, §§ 2.61-2.67

Any permitted disclosure made must be limited to the information that is necessary to carry out the purpose of the disclosure. 42 C.F.R. § 2.13(a). Employees of a prosecutor office must follow the restrictions on disclosure in 42 C.F.R. even if they believe that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency or official or other government official, has obtained a subpoena, or asserts any other justification for an unpermitted disclosure. § 2.13(b). In addition, employees cannot acknowledge the presence of an identified participant in the facility for SUD, treatment, or referral, and any answer to a request for a disclosure of patient records which is not permissible must be made in a



way that will not affirmatively reveal that an identified individual has been, or is being, diagnosed or treated for a SUD. § 2.13(c).

A prosecutor's office may disclose otherwise prohibited information if a participant provides written consent to the disclosure that includes all the required components. See 42 C.F.R. § 2.31(a).

The HIPAA Privacy Rule permits uses and disclosures for treatment, payment and health care operations as well as certain other disclosures without the individual's prior authorization. HIPAA covered entities are health plans, health care clearinghouses and health care providers who transmit health information in electronic form (*i.e.*, via computer-based technology) in connection with transactions for which HHS has adopted a HIPAA standard in 45 CFR Part 162. See 45 C.F.R. § 160.103. If a substance abuse treatment program transmits health information electronically in connection with one or more HIPAA transactions under Part 162 (which includes submission to claims to health plans, coordination of benefits with health plans, inquiries to health plans regarding eligibility, coverage or benefits or status of health care claims, transmission of enrollment and other information related to payment to health plans, referral certification and authorization), then the program must comply with the Privacy Rule. HIPAA covered entities also include business associates of HIPAA covered entities.

A covered entity may, without the individual's authorization:

- Use or disclose protected health information for its own treatment, payment, and health care operations activities. 45 C.F.R. § 164.506(c)(1).
- Disclose protected health information for the treatment activities of any health care provider (including providers not covered by the Privacy Rule). § 164.506(c)(2).
- Disclose protected health information to another covered entity or a health care provider (including providers not covered by the Privacy Rule) for the payment activities of the entity that receives the information. § 164.506(c)(3).
- Disclose protected health information to another covered entity for certain health care operation activities of the entity that receives the information if:
 - Each entity either has or had a relationship with the individual who is the subject of the information, and the protected health information pertains to the relationship, § 164.506(c)(4)(i); and
 - The disclosure is for a quality-related health care operations activity (*i.e.*, the activities listed in paragraphs (1) and (2) of the definition of "health care operations" at § 164.501) or for the purpose of health care fraud and abuse detection or compliance, § 164.506(c)(4)(ii).
- If the covered entity participates in an organized health care arrangement (OHCA), disclose protected health information about an individual to another covered entity that participates in the OHCA for any joint health care operations of the OHCA. § 164.506(c)(5).

Protected health information regarding involvement in the patient's care and notification purposes requires an opportunity for the individual to agree or to object. 45 C.F.R. § 164.510(b)(1):

- If the patient is available and has the capacity to make health decisions, and if the patient agrees or does not object when given the opportunity, a health care provider may discuss the patient's health



information with a family member, friend, or other person involved in the patient's care or payment for care. § 164.510(b)(2). If in his professional judgment, the provider decides that the patient does not object, the provider can share the information as well. *Id.*

- If the patient is incapacitated or not present, the health provider can share the patient's health information with family, friends, or other involved in the patient's care or payment for care, if the health provider determines, based on his/her professional judgment – that this communication is in the best interest of the patient. § 164.510(b)(3). However, the provider must only share information that the involved person needs to know about the patient's care or payment. *Id.*
- If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in (b)(1), protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual known to the covered entity. § 164.510(b)(5).

A covered entity may also use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts. 45 C.F.R. § 164.510(b)(4).

Part 2, not HIPAA, was designed to protect information that identifies a person as a patient or an applicant for SUD treatment. As a result, Part 2 provides greater protection to SUD information, which encourages individuals to seek out and stay in alcohol or drug treatment:

- Under HIPAA, law enforcement authorities could seize patient records with subpoenas and general court orders and use them to prosecute people in addiction treatment programs. While HIPAA does not provide significant protections against information in SUD records being routinely seized to investigate and prosecute patients in substance use treatment, Part 2 prevents treatment programs from releasing patients' SUD information to law enforcement authorities, and judicial or administrative bodies, without a special court order, 42 C.F.R. §§ 2.61–2.67.
- Patients undergoing alcohol and/or drug treatment will be more likely to lose the ability to obtain health insurance under HIPAA. HIPAA allows disclosures of SUD treatment information to health plans without the patient's consent, while Part 2 only allows disclosure of this type of treatment information to insurers with the patient's written consent. Part 2 also limits the disclosed patient information to just that amount of information that is needed to accomplish the purpose of the disclosure.

Ethical Duties

While a prosecutor does not directly represent individual clients, the following ethical guidelines may provide insight into whether and how a prosecutor should disclose information about an overdose incident to family members, acquaintances or other individuals. A prosecutor who works collaboratively in partnership with other law enforcement professionals and social service agencies to identify and address the needs of overdose survivors is interested in seeking the best outcome for this individual. This interest is aligned with an attorney's ethical duty to provide legal advice and representation that is in the best interest of the client.

Under both the Wisconsin's Rules of Professional Conduct for Attorneys, Ch. 20, Rule 1.6 and ABA's Model Rules of Professional Conduct, Rule 1.6, a lawyer has the ethical duty to not reveal information relating to the



representation of a client unless the client gives informed consent. However, a lawyer may reveal information in relation to the representation of a client to the extent the lawyer reasonably believes necessary:

- To prevent reasonably likely death or substantial bodily harm
- To prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the employee's services
- To secure legal advice about the lawyer's conduct under these rules
- To establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client
- To comply with other law or a court order; or
- To detect and resolve conflicts of interest, but only if the revealed information would not compromise the attorney-client privilege or otherwise prejudice the client.

While the ABA rule continues to state that a lawyer may reveal information related to the representation of a client to the extent the lawyer reasonably believes necessary to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer's services, *see* MODEL RULES OF PROF'L CONDUCT r. 1.6(b)(2) (AM. BAR ASS'N 2020), the Wisconsin rule states that the lawyer should reveal information relating to the representation of a client if he or she reasonably believes it is necessary to prevent the client from committing a criminal or fraudulent act that the lawyer reasonably believes is likely to result in death or substantial bodily harm or in substantial injury to the financial interest or property of another, *see* WISCONSIN'S RULE OF PROF'L CONDUCT FOR ATTORNEYS, S.C.R., ch. 20, r. 1.6(b)(2020).

ABA's Criminal Justice Standards for the Prosecution Function are intended to be entirely consistent with the ABA's Model Rules of Professional Conduct and are not intended to modify a prosecutor's obligations under applicable rules, statutes, or the constitution. When protected confidences are involved, a prosecutor or former prosecutor should not make disclosure without consent from the prosecutor's office. CRIMINAL JUSTICE STANDARDS FOR THE PROSECUTION FUNCTION § 3-1.11(c) (AM. BAR ASS'N 2017). Subject to ethical rules and the confidentiality that criminal matters sometimes require, and unless prohibited by law or court order, the prosecutor should give information of the status of matters in which they are involved to victims and witnesses who request it. § 3-3.4(k).

NDAA's National Prosecution Standards states that a prosecutor should work with other law enforcement agencies to cooperate with victim advocates for the benefit of providing direct and referral services to victims of crime and assist in the protection of a victim's right to privacy regarding a victim's Social Security number, birth date, address, telephone number, place of employment, name (when the victim is a minor or a victim of sexual assault), or any other personal information unless either a court finds it necessary to that proceeding or disclosure is required by law. NAT'L PROSECUTION STANDARDS § 2-9.4 (NAT'L DIST. ATTORNEYS ASSOC. 2009).

Although who constitutes “victims of crime” is not explicitly explained, the first subsection of § 2-9 Relations with Victims, which precedes § 2-9.4’s “victims of crime” language, refers to “victims of violent crimes, serious felonies, or any actions where it is likely the victim may be the object of physical or other forms of retaliation” as the subject of the section. See § 2-9.1. The subsequent subsections, including § 2-9.4, then uses only the blanket terms “victims of crime” and “victims” in its text without other possible definitions.

Under the statutory construction rules of *ejusdem generis* and *noscitur a sociis*, this suggests that the general term “victims of crime” in the subsequent § 2-9.4 includes only the previous specific references of “victims of violent crimes, serious felonies, or any actions where it is likely the victim may be the object of physical or other forms of retaliation” in § 2-9.1.

Given this definition of “victims of crime,” a witness may be included as a victim of crime in § 2-9.4 if the witness was harmed or injured from an action where it is likely the witness may be the object of physical or other forms of retaliation. Although the NDAA discusses victims and witnesses in separate sections, see § 2-9 (discussing prosecutorial relations with victims); § 2-10 (discussing prosecutorial relations with witnesses), the commentary provided after both sections discusses prosecutorial protection of victims and witnesses as one type of protection that is needed by both, albeit for different reasons. The commentary notes that one of the greatest needs of victims and witnesses is the assurance of their safety since they are most vulnerable to threats, harassment, and intimidation. NAT’L PROSECUTION STANDARDS 35 (NAT’L DIST. ATTORNEYS ASSOC. 2009). Similarly, § 2-10.9 states that a prosecutor should assign a high priority to the investigation and prosecution of any type of witness intimidation, harassment, coercion, or retaliation, including any such conduct or threatened conduct against family members or friends. Accordingly, the guidelines appear to suggest that a witness’ personal information should be protected unless disclosure is necessary.

CARES Act

Because additional regulations enacting the CARES Act amendments are forthcoming by March 27, 2021, their impact at this point is not fully known.

The practical impact on many Part 2 programs that are also HIPAA covered entities will be somewhat limited in nature. The major impacts of the CARES Act on these entities are as follows:

- Part 2 programs will now be able to use and disclose Part 2 records for treatment, payment and health care operations in accordance with HIPAA as long as they have received the patient’s initial written consent, which only needs to be obtained once, but may be revoked by the patient at any time. CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT, PUB. L. NO 116-136, § 3221(b), 134 STAT 281 (Mar. 27, 2020).
- Using a weaker HIPAA standard, information can be disclosed to any health care provider, even to those who do not have any treating provider relationship with the patient and can be disclosed for functions that are not directly related to the provision of health care. See generally HHS, Office for Civil Rights, *OCR HIPAA Privacy: Uses and Disclosures for Treatment, Payment, and Health Care Operations* (Apr. 3, 2003), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/sharingfort_po.pdf (provides definition and examples of “health care operations”).



- Current standards in Part 2 for written consent would appear to need to be relaxed to permit a one-time, ongoing consent for such purposes.
- Once disclosed for such purposes, the information no longer appears to be subject to the more stringent Part 2 requirements and would only be subject to HIPAA's requirements, but this is not entirely clear. § 3221(b).
- Limited Part 2 SUD information not already subject to HIPAA can be disclosed to certain public health authorities as long as information must be de-identified in accordance with HIPAA's de-identification standards prior to disclosure. § 3221(c).
- Breach notification will be required for the impermissible disclosure of unsecured SUD records. This will not be a new obligation for covered entities whose SUD records were already protected health information subject to HIPAA. § 3221(h).
- The penalties for a violation of the Part 2 requirements will now be the same as what a covered entity faces for a HIPAA violation. § 3321(f).

Additional guidance from SAMHSA is forthcoming and will hopefully address outstanding questions, such as what that written consent must look like and contain, and whether disclosures for such purposes continue to be subject to Part 2 or only the requirements of HIPAA. See *CARES Act Modifies Confidentiality Protections for Substance Use Disorder Records*, HALL, RENDER, KILLIAN, HEALTH & LYMAN, P.C.: HEALTH INFORMATION TECHNOLOGY BLOG (Apr. 13, 2020), <https://www.hallrender.com/2020/04/13/cares-act-modifies-confidentiality-protections-for-substance-use-disorder-records/>.

Information Data-Sharing Tools

Some jurisdictions have addressed the potential challenges in sharing information about opioid and drug overdose incidents by forming a data-sharing partnership that outlines how and when certain types of data will be shared among the various members of this partnership. These data-sharing partnerships often include professionals across various agencies, such as law enforcement, medical practitioners, social service agencies, prosecutor offices, and others who share the common goal of reducing drug-related overdose incidents.

The specific types of data that may be shared and actionable procedures that may result can vary. For example, prosecutors and other partners may form a law enforcement assisted diversion (LEAD) or other such program, in which the various partners seek to offer entry into a diversion program that includes substance use treatment and other social services. Other jurisdictions may choose to form an overdose fatality review team, in which certain agencies meet and collectively discuss and strategize how to prevent or reduce future drug overdose incidents. Sometimes the specific data-sharing protocols and procedures, including whether certain data will first be de-identified by a specific party before it is shared, are captured in a formal data sharing agreement or memorandum of understanding.

Part 2 has a special provision, § 2.35, for when criminal justice entities, like law enforcement, make a patient's participation in a Part 2 program as part of a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody (*i.e.*, diversion program, a drug



court program or other treatment-based alternative to incarceration). A Part 2 program can then share information with criminal justice entities if a patient’s prior consent is obtained and the disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor a participant’s progress. See 42 C.F.R. § 2.35(a)(1). These requirements ensure that treatment information is not used to substantiate prosecutions. If a Part 2 program is sharing protected SUD information that identifies participants to law enforcement, the Part 2 program must obtain consent from the patient, either as a condition of admission to the program or before the release of information, that meets the requirements of 42 C.F.R. § 2.31. See § 2.35(a)(2).

Most admissions into programs such as mental health courts or diversion programs require a potential participant to provide permission to share information between criminal justice and behavioral healthcare clinicians as a condition of admission to the program. See *Information Sharing in Criminal Justice-Mental Health Collaborations*, U.S. DEP’T OF JUST. 1, 8 (2010), https://bja.ojp.gov/sites/g/files/xyckuh186/files/Publications/CSG_CJMH_Info_Sharing.pdf.

Many jurisdictions also attempt to get the court to obtain the defendant’s permission for disclosure of health information as a condition of community supervision or include a provision in the court order that permits the supervising officer to obtain health-related information when necessary to monitor compliance with the conditions of release. This facilitates the exchange of information between the covered entity that is providing treatment and the probation officer. *Id* at 3. The usual Part 2 rules permitting the participant to revoke consent “at will” do not apply. See § 2.35(c).

In *United States v. White*, the defendant was convicted of drunk driving and was evaluated by a mental health center, where the defendant disclosed information indicating a history of substance abuse. During sentencing, the court ordered defendant to complete a substance abuse treatment program and to disclose her conviction and history of substance abuse to the county’s health department, and social and rehabilitation services to facilitate defendant’s participation and completion of the substance abuse treatment program. The court held that § 2.35 applies to the case because the information concerning defendant’s substance abuse history will be disclosed in connection with the judge’s performance of his official duties of pronouncing and imposing sentences. *United States v. White*, 902 F. Supp. 1347, 1352 (D. Kan. 1995). Although this case involves the disclosure of SUD information to a judge, it shows how § 2.35 would apply to disclosure of information to law enforcement involved with a diversion program like a LEAD program.

Law Enforcement Assisted Diversion (LEAD):

- “LEAD begins with initial contact between a police officer and someone who would typically be arrested for a low-level offense (e.g., drug possession). The officer exercises his or her discretion to determine whether the person would be a good candidate for diversion; if so, the individual is arrested but is referred to treatment or other social services, such as housing support or job training.” (Goodison, Sean E., Michael J. D. Vermeer, Jeremy D. Barnum, Dulani Woods, and Brian A. Jackson,

Law Enforcement Efforts to Fight the Opioid Crisis: Convening Police Leaders, Multidisciplinary Partners, and Researchers to Identify Promising Practices and to Inform a Research Agenda. Santa Monica, CA: RAND Corporation, 2019. https://www.rand.org/pubs/research_reports/RR3064.html, available at: [https://www.rand.org/content/dam/rand/pubs/research_reports/RR3000/RR3064/RAND_RR3064.p df](https://www.rand.org/content/dam/rand/pubs/research_reports/RR3000/RR3064/RAND_RR3064.pdf))

- “When an eligible individual is arrested for a low-level drug offense (either possession of a controlled substance or sale of small amounts of narcotics for subsistence purposes) or for prostitution in Belltown, a trained police officer may elect to refer that individual to a LEAD case manager instead of booking the arrested individual into jail. However, per the protocol agreed upon by LEAD stakeholders, not every low-level drug offender is eligible for LEAD.” (Beckett, K.

(2014). *Seattle's Law Enforcement Assisted Diversion Program: Lessons learned from the first two years*. Seattle, WA: University of Washington, available at: <https://www.fordfound.org/media/2543/2014-lead-process-evaluation.pdf>).

- “Currently, there are 20 LEAD programs in operation across the nation and more than 40 sites exploring, developing, or launching a LEAD program (LEAD National Support Bureau, undated). Initial assessments suggest that the effect of these law enforcement–led initiatives has been positive” (Goodison, et al., 2019, *citing to Law Enforcement Assisted Diversion National Support Bureau, homepage, undated*. As of July 23, 2019: <https://www.leadbureau.org>; Police Executive Research Forum, *Building Successful Partnerships Between Law Enforcement and Public Health Agencies to Address Opioid Use*, Washington, D.C.: Office of Community Oriented Policing Services, U.S. Department of Justice, 2016. As of July 23, 2019: <https://ric-zai-inc.com/Publications/cops-p356-pub.pdf>).
- “The LEAD protocol does not authorize any formal or punitive sanctions for “non-compliance.” Although the King County Prosecuting Attorney’s Office and the Seattle Attorney’s office retain their authority to file charges against LEAD participants for past crimes or crimes they commit while in LEAD, prosecutors have committed to working in cooperation with LEAD, which means exercising their discretion to not bring charges against LEAD participants where doing so will enhance LEAD’s efficacy. At regularly held work group meetings, law enforcement officers, case managers and prosecutors share information about LEAD clients so that each of these actors make informed decisions in matters pertaining to LEAD clients. In particular, these meetings were useful to prosecutors weighing whether to file charges LEAD clients acquired subsequent to their enrollment in LEAD.” (Beckett, K. (2014). *Seattle's Law Enforcement Assisted Diversion Program: Lessons learned from the first two years*. Seattle, WA: University of Washington.)

Pennsylvania’s Opioid Response:

- “The Heroin Response Strategy (HRS) is a public health–public safety partnership between the High Intensity Drug Trafficking Area (HIDTA) program and the CDC.
- Beginning in 2015 among five HIDTAs in 15 states, the HRS mission—to reduce rates of fatal and non- fatal overdose by supporting collaborative efforts between public health and public safety agencies at the federal, state, and local level—expanded in 2017 to include ten HIDTAs in 22 states.

- The HRS addresses increasing levels of overdose in a multi-faceted and cross-disciplinary manner—to include law enforcement, response, treatment and recovery, and prevention. Specifically, the HRS provides funding for a Drug Intelligence Officer and a Public Health Analyst in each participating state to work with public health and public safety agencies to improve data sharing that informs the scope of the opioid problem, increase sharing of criminal intelligence, and either support existing or help develop programs designed to fulfill the HRS mission
- The DEA 360 Initiative was implemented in November 2016 as an innovative three-pronged approach to combating heroin/opioid use through:
 - 1) coordinating law enforcement actions against drug cartels and heroin traffickers in specific communities
 - 2) Diversion Control enforcement actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug manufacturers, wholesalers, pharmacies, and practitioners; and
 - 3) Community Outreach through local partnerships that empower communities to take back affected neighborhoods after enforcement actions and prevent the same problems from reoccurring.
- Pittsburgh was the pilot city for the 360 Strategy, and during the inaugural year, more than 200 presentations, meetings, briefings, and community engagements occurred. The 360 Strategy in Pittsburgh resulted in the establishment of relationships with community partners, treatment providers, educators, policy makers, and registrants that continues to foster information sharing, resource discussion, and integrated strategies to address the opioid crisis in the region. In May 2018, the 360 Strategy was initiated in Philadelphia with similar efforts and results anticipated.”
- (<https://www.overdosefreepa.pitt.edu/wp-content/uploads/2018/10/PA-Opioid-Report-Final.pdf>)

Baltimore Overdose Detection Mapping Application (ODMAP):

- “To address the lack of real-time data and information sharing related to the opioid crisis, the Washington/Baltimore High Intensity Drug Trafficking Area (HIDTA) developed the Overdose Detection Mapping Application Program (ODMAP), which allows real-time data on overdoses to be compiled and shared across a platform to a variety of stakeholders. In the Baltimore HIDTA’s case, it is able to populate data from Washington, DC, Virginia, Maryland and parts of West Virginia.” (National District Attorneys Association, The Opioid Epidemic: A State and Local Prosecutor Response, October 12, 2018, *available at* <https://ndaa.org/wp-content/uploads/NDAA-Opioid-White-Paper.pdf>)
- “ODMAP facilitates data collaboration by providing stakeholders access to a centralized platform in which to input information about overdose incidents as they occur. This allows for real-time monitoring of overdose trends, identification of hot spots or incident spikes, and comparison of incidents with other relevant data sources (Beeson, 2018)” (Goodison, et al., 2019)
- “Most American jurisdictions do not share data among law enforcement, fire departments, and emergency medical services, and even fewer do so in real time. ODMAP eliminates this data-sharing dearth by centralizing all agencies’ data relating to overdoses within one platform” (Beeson, J., DMAP: A Digital Tool to Track and Analyze Overdoses, May 14, 2018, *available at* <https://nij.ojp.gov/topics/articles/odmap-digital-tool-track-and-analyze-overdoses>)

- The type of patient information provided by Level 2 ODMAP data does not include any personally identifiable information that would violate the privacy protections under 42 C.F.R. Part 2, particularly if the individuals utilizing this substance abuse history qualify as "covered entities."¹
- More information can be found at: <http://www.hidta.org/odmap/>, <https://ndaa.org/wp-content/uploads/NDAA-Opioid-White-Paper.pdf>

ODMAP Process:

- **LEVEL 1 - DATA COLLECTION AND AGENCY ADMINISTRATION INTERFACE:** Level 1 is a web interface which can be accessed from any device and through a CAD system. The system was designed to minimize the effort and time required by a first responder to enter data. It will report date and time when accessed, and if the Level 1 user accesses ODMAP in the field, the system will default to the GPS coordinates of the device for the location, or they can enter an address. The user must record whether or not the overdose incident is fatal or non-fatal and the extent to which naloxone or an overdose reversal drug was administered, in all taking seconds and provides the Level 1 user a confirmation when entered.
- **LEVEL 1 - API DATA COLLECTION:** An Application Programming Interface (API) is a popular method for stakeholder agencies to contribute data without creating additional (manual) reporting or processes. The API allows for data integration by connecting with the agency or state's Record Management Software (RMS) to ODMAP. An API allows for the direct, automated integration of the two systems.
- ODMAP connects to diverse fields such as EMS, Law Enforcement, and Health. EMS has adopted the National Emergency Medical Services Information Systems (NEMSIS). Law Enforcement does not have an industry adopted standard similar to NEMSIS, although, there have been attempts at utilizing

¹"The information available to Level 2 users of ODMAP does not relate to patient records concerning substance use disorder diagnosis, treatment, or referral to treatment. Accordingly, 42 CFR Part 2 is not implicated in the use of ODMAP as it currently operates...Have any federal or state courts addressed ODMAP in any capacity? There are no reported state or federal cases in Westlaw as of February 29, 2020. 74 E.g., Jeff Mordock, N.Y. police now treat drug overdose sites as crime scenes in bid to take down dealers, The Washington Times (February 19, 2019), available at <https://www.washingtontimes.com/news/2019/feb/19/newyork-opioid-overdose-sites-now-crime-scenes/> (last accessed March 3, 2020). 75 45 CFR §§ 164.502(b) and 164.514(d). 76 See page 8. ODMAP and Protected Health Information Under HIPAA: Guidance Document 17 This project was supported by Grant No. G1999ONDPC03A awarded by the Office of National Drug Control Policy, Executive Office of the President. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government. © 2020 The Legislative Analysis and Public Analysis Association. This document is intended for informational purposes only and does not constitute legal advice or opinion. Research is current through February 2020. Are there any publicly available legal opinions addressing ODMAP and the Privacy Rule, and what are the conclusions? As of February 2020, the Offices of the Attorney General in three states— Maryland, South Carolina, and Nevada—have issued legal memoranda analyzing the interplay between ODMAP and HIPAA. In each opinion, the respective attorney general's office concludes that the Privacy Rule allows the reporting of overdose information from covered entity Level 1 ODMAP users to Level 2 ODMAP users."
<http://www.odmap.org/Content/docs/training/featured/ODMAP-Data-Privacy-Guidance-Document.pdf>

the National Information Exchange Model (NIEM) standards, it is not implemented nationally. As a result, ODMAP developed a custom API which is simple to consume across disciplines.

- LEVEL 2 - NATIONAL MAP: ODMAP data is controlled unclassified information (CUI) and may only be released to authorized personnel. Recipients of this information must have a need and right to know the information in the performance of their criminal justice and public health functions. The ODMAP dashboard (Level 2) is designed as a tool for decision-makers to be able to view and analyze the data, nationwide, submitted to ODMAP. Per the ODMAP Teaming Agreement, ODMAP shall only be used for its intended purposes.
- (<http://www.odmap.org/#how>).

Other Local Alliances/Partnerships

- Chittenden County Opioid Alliance: this partnership is comprised of police and other local partners who have formed 4 “action teams,” who work together to achieve the following goals:
 - “Community level prevention
 - Treatment access and recovery support
 - Working recovery
 - CommunityStat rapid intervention” (Trabert, E., Frohwein A., Robin L., Silverman J., Coldren J., Kunard L., Saizow H., “Opioid Data Initiative,” CAN Analysis & Solutions, Dec. 2018).
- Law enforcement professionals in Madison, Wisconsin regularly share information with the city’s mayor, the county public health department, and additionally post certain information publicly on the police department’s website (Trabert, E., Frohwein A., Robin L., Silverman J., Coldren J., Kunard L., Saizow H., “Opioid Data Initiative,” CAN Analysis & Solutions, Dec. 2018).
- The New York-based Rx Stat Operations Group is comprised of 25 agencies that meet on a quarterly basis to share information that may help reduce drug overdose incidents (<https://www.nydailynews.com/new-york/changing-tactics-nypd-focuses-drug-users-not-prison-article-1.3181986>)
- Overdose fatality reviews: the National Center for State Courts (NCSC) has compiled a series of resources detailing the scope and objectives of various overdose fatality review teams that exist around the country: <https://www.ncsc.org/information-and-resources/companion-sites/nerjoi/ofr-team>
 - Maryland’s Overdose Fatality Review Program: “
 - “Program Goals:
 1. Identify missed opportunities for prevention and gaps in system
 2. Build working relationships between local stakeholders on overdose prevention and improve overall collaboration and communication within a jurisdiction
 3. Recommend policies, programs, or changes to law that prevent overdose deaths and better serve people at risk for overdose



4. Inform local and state overdose and opioid misuse prevention strategy
 - Local OFR Outcomes to Date:
 - Improvements to the quality of referral systems
 - Increased focus on outreach to families to provide overdose prevention & treatment services by local health departments and other providers
 - Identification of new target audiences for Overdose Response Program (naloxone) trainings
 - Increased awareness of member agency staff of overdose related issues and Overdose Response Program training for member agency staff
 - Changes to intake questionnaires to include questions about overdose history” (https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Pages/OFR-.aspx)
 - Winnebago County, WI Health Department’s Overdose Fatality Review
 - Established in 2018, this team that is comprised of more than 20 local agencies meets on a monthly basis to discuss fatal drug overdose incidents that have occurred within Winnebago County (https://www.co.winnebago.wi.us/sites/default/files/uploaded-files/overdose_fatality_review_one_pager.pdf)



Statutes

42 C.F.R. § 2.11 (2020), DEFINITIONS.

Qualified service organization means an individual or entity who:

- (1) Provides services to a part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and
- (2) Has entered into a written agreement with a part 2 program under which that individual or entity:
 - (i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and
 - (ii) If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

42 C.F.R. § 2.12 (2020), APPLICABILITY.

(a) *General*—

- (1) *Restrictions on disclosure.* The restrictions on disclosure in the regulations in this part apply to any information, whether or not recorded, which:
 - (i) Would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person; and
 - (ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.
- (2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290dd-2(c)) applies to any information, whether or not recorded, which is drug abuse information obtained by a

federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* A program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Participating provider in the Medicare program;

(ii) Authorization to conduct maintenance treatment or withdrawal management; or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of federal financial assistance in any form, including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment; or

(ii) Conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, receives federal funds which could be (but are not necessarily) spent for the substance use disorder program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions—*

(1) *Department of Veterans Affairs.* These regulations do not apply to information on substance use disorder patients maintained in connection with the Department of Veterans Affairs' provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38, U.S.C. Those



records are governed by 38 U.S.C. 7332 and regulations issued under that authority by the Secretary of Veterans Affairs.

(2) *Armed Forces.* The regulations in this part apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

- (i) Any interchange of that information within the Armed Forces; and
- (ii) Any interchange of that information between the Armed Forces and those components of the Department of Veterans Affairs furnishing health care to veterans.

(3) *Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.* The restrictions on disclosure in the regulations in this part do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients with substance use disorders if the communications are:

- (i) Within a part 2 program; or
- (ii) Between a part 2 program and an entity that has direct administrative control over the program.

(4) *Qualified service organizations.* The restrictions on disclosure in the regulations in this part do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.

(5) *Crimes on part 2 program premises or against part 2 program personnel.* The restrictions on disclosure and use in the regulations in this part do not apply to communications from part 2 program personnel to law enforcement agencies or officials which:

- (i) Are directly related to a patient's commission of a crime on the premises of the part 2 program or against part 2 program personnel or to a threat to commit such a crime; and
- (ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in the regulations in this part do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program



including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

42 C.F.R. § 2.13 (2020), CONFIDENTIALITY RESTRICTIONS AND SAFEGUARDS.

(a) *General.* The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in the regulations in this part apply whether or not the part 2 program or other lawful holder of the patient identifying information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency or official or other government official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by the regulations in this part.

(c) *Acknowledging the presence of patients: Responding to requests.*

(1) The presence of an identified patient in a health care facility or component of a health care facility which is publicly identified as a place where only substance use disorder diagnosis, treatment, or referral for treatment is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of this part or if an authorizing court order is entered in accordance with subpart E of this part. The regulations permit acknowledgement of the presence of an identified patient in a health care facility or part of a health care facility if the health care facility is not publicly identified as only a substance use disorder diagnosis, treatment, or referral for treatment facility, and if the acknowledgement does not reveal that the patient has a substance use disorder.

(2) Any answer to a request for a disclosure of patient records which is not permissible under the regulations in this part must be made in a way that will not affirmatively reveal that an identified individual has been, or is being, diagnosed or treated for a substance use disorder. An inquiring party may be provided a copy of the regulations in this part and advised that they restrict the disclosure of substance use disorder patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient.

42 C.F.R. §2.20 (2020), RELATIONSHIP TO STATE LAWS.

The statute authorizing the regulations in this part (42 U.S.C. 290dd-2) does not preempt the field of law which they cover to the exclusion of all state laws in that field. If a disclosure permitted under the regulations in this part is prohibited under state law, neither the regulations in this part nor the authorizing statute may

be construed to authorize any violation of that state law. However, no state law may either authorize or compel any disclosure prohibited by the regulations in this part.

42 C.F.R. § 2.31 (2020), Consent Requirements.

42 C.F.R. § 2.31 (2020), CONSENT REQUIREMENTS.

(a) *Required elements for written consent.* A written consent to a disclosure under the regulations in this part may be paper or electronic and must include:

(1) The name of the patient.

(2) The specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.

(3) How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.

(4) (i) The name(s) of the individual(s) to whom a disclosure is to be made; or

(ii) *Entities with a treating provider relationship with the patient.* If the recipient entity has a treating provider relationship with the patient whose information is being disclosed, such as a hospital, a health care clinic, or a private practice, the name of that entity; or

(iii) *Entities without a treating provider relationship with the patient.*

(A) If the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is a third-party payer, the name of the entity; or

(B) If the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is not covered by paragraph (a)(4)(iii)(A) of this section, such as an entity that facilitates the exchange of health information or a research institution, the name(s) of the entity(-ies); and

(1) The name(s) of an individual participant(s); or

(2) The name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or

(3) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.

(i) When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (see §2.13(d)).

(ii) [Reserved]

(5) The purpose of the disclosure. In accordance with §2.13(a), the disclosure must be limited to that information which is necessary to carry out the stated purpose.

(6) A statement that the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer

(7) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.

(8) The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under §2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.

(9) The date on which the consent is signed.

(b) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through reasonable diligence could be known, by the individual or entity holding the records to be materially false.

42 C.F.R. § 2.35 (2020), DISCLOSURES TO ELEMENTS OF THE CRIMINAL JUSTICE SYSTEM WHICH HAVE REFERRED PATIENTS.

(a) A part 2 program may disclose information about a patient to those individuals within the criminal justice system who have made participation in the part 2 program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(6) of this section which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) Duration of consent. The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the part 2 program, the patient, and the individual(s) within the criminal justice system who will receive the disclosure consider pertinent.

(c) Revocation of consent. The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) Restrictions on re-disclosure and use. An individual within the criminal justice system who receives patient information under this section may re-disclose and use it only to carry out that individual's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

42 C.F.R. § 2.51 (2020), MEDICAL EMERGENCIES.

(a) *General rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained.

(b) *Special rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the part 2 program shall document, in writing, the disclosure in the patient's records, including:

- (1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
- (2) The name of the individual making the disclosure;
- (3) The date and time of the disclosure; and
- (4) The nature of the emergency (or error, if the report was to FDA).

42 C.F.R. § 2.52 (2020), RESEARCH.

(a) Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be disclosed by the part 2 program or other lawful holder of part 2 data, for the purpose of conducting scientific research if the individual designated as director or managing director, or individual otherwise vested with authority to act as chief executive officer or their designee makes a determination that the recipient of the patient identifying information:

- (1) If a HIPAA-covered entity or business associate, has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule at 45 CFR 164.508 or 164.512(i), as applicable; or
- (2) If subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), either provides documentation that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.101(b) and any successor regulations; or
- (3) If both a HIPAA covered entity or business associate and subject to the HHS regulations regarding the protection of human subjects, has met the requirements of paragraphs (a)(1) and (2) of this section; and
- (4) If neither a HIPAA covered entity or business associate or subject to the HHS regulations regarding the protection of human subjects, this section does not apply.

(b) Any individual or entity conducting scientific research using patient identifying information obtained under paragraph (a) of this section:

- (1) Is fully bound by the regulations in this part and, if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part.
- (2) Must not re-disclose patient identifying information except back to the individual or entity from whom that patient identifying information was obtained or as permitted under paragraph (c) of this section.
- (3) May include part 2 data in research reports only in aggregate form in which patient identifying information has been rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder.
- (4) Must maintain and destroy patient identifying information in accordance with the security policies and procedures established under §2.16.
- (5) Must retain records in compliance with applicable federal, state, and local record retention laws.

(c) *Data linkages*—

(1) *Researchers.* Any individual or entity conducting scientific research using patient identifying information obtained under paragraph (a) of this section that requests linkages to data sets from a data repository(-ies) holding patient identifying information must:

- (i) Have the request reviewed and approved by an Institutional Review Board (IRB) registered with the Department of Health and Human Services, Office for Human Research Protections in accordance with 45 CFR part 46 to ensure that patient privacy is considered and the need for identifiable data is justified. Upon request, the researcher may be required to provide evidence of the IRB approval of the research project that contains the data linkage component.
- (ii) Ensure that patient identifying information obtained under paragraph (a) of this section is not provided to law enforcement agencies or officials.

(2) *Data repositories.* For purposes of this section, a data repository is fully bound by the provisions of part 2 upon receipt of the patient identifying data and must:

- (i) After providing the researcher with the linked data, destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the patient identifying information non-retrievable in a manner consistent with the policies and procedures established under §2.16 Security for records.



(ii) Ensure that patient identifying information obtained under paragraph (a) of this section is not provided to law enforcement agencies or officials.

(2) Except as provided in paragraph (c) of this section, a researcher may not redisclose patient identifying information for data linkages purposes.

42 C.F.R. § 2.53 (2020), AUDIT AND EVALUATION.

(a) *Records not copied or removed.* If patient records are not downloaded, copied or removed from the premises of a part 2 program or other lawful holder, or forwarded electronically to another electronic system or device, patient identifying information, as defined in §2.11, may be disclosed in the course of a review of records on the premises of a part 2 program or other lawful holder to any individual or entity who agrees in writing to comply with the limitations on re-disclosure and use in paragraph (d) of this section and who:

(1) Performs the audit or evaluation on behalf of:

(i) Any federal, state, or local governmental agency that provides financial assistance to a part 2 program or other lawful holder, or is authorized by law to regulate the activities of the part 2 program or other lawful holder;

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review, or such individual's or entity's or quality improvement organization's contractors, subcontractors, or legal representatives.

(2) Is determined by the part 2 program or other lawful holder to be qualified to conduct an audit or evaluation of the part 2 program or other lawful holder.

(b) *Copying, removing, downloading, or forwarding patient records.* Records containing patient identifying information, as defined in §2.11, may be copied or removed from the premises of a part 2 program or other lawful holder or downloaded or forwarded to another electronic system or device from the part 2 program's or other lawful holder's electronic records by any individual or entity who:

(1) Agrees in writing to:

(i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under §2.16;

(ii) Retain records in compliance with applicable federal, state, and local record retention laws; and





(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation on behalf of:

(i) Any federal, state, or local governmental agency that provides financial assistance to the part 2 program or other lawful holder, or is authorized by law to regulate the activities of the part 2 program or other lawful holder; or

(ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review, or such individual's or entity's or quality improvement organization's contractors, subcontractors, or legal representatives.

(c) Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation.

(1) Patient identifying information, as defined in §2.11, may be disclosed under paragraph (c) of this section to any individual or entity for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the individual or entity agrees in writing to comply with the following:

(i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under §2.16;

(ii) Retain records in compliance with applicable federal, state, and local record retention laws; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section.

(2) A Medicare, Medicaid, or CHIP audit or evaluation under this section includes a civil or administrative investigation of a part 2 program by any federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP and includes administrative enforcement, against the part 2 program by the government agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(3) An audit or evaluation necessary to meet the requirements for a CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must be conducted in accordance with the following:





AEQUITAS

(i) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must:

(A) Have in place administrative and/or clinical systems; and

(B) Have in place a leadership and management structure, including a governing body and chief executive officer with responsibility for oversight of the organization's management and for ensuring compliance with and adherence to the terms and conditions of the Participation Agreement or similar documentation with CMS; and

(ii) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must have a signed Participation Agreement or similar documentation with CMS, which provides that the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE):

(A) Is subject to periodic evaluations by CMS or its agents, or is required by CMS to evaluate participants in the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) relative to CMS-defined or approved quality and/or cost measures;

(B) Must designate an executive who has the authority to legally bind the organization to ensure compliance with 42 U.S.C. 290dd-2 and this part and the terms and conditions of the Participation Agreement in order to receive patient identifying information from CMS or its agents;

(C) Agrees to comply with all applicable provisions of 42 U.S.C. 290dd-2 and this part;

(D) Must ensure that any audit or evaluation involving patient identifying information occurs in a confidential and controlled setting approved by the designated executive;

(E) Must ensure that any communications or reports or other documents resulting from an audit or evaluation under this section do not allow for the direct or indirect identification (*e.g.*, through the use of codes) of a patient as having or having had a substance use disorder; and

(F) Must establish policies and procedures to protect the confidentiality of the patient identifying information consistent with this part, the terms and conditions of the Participation Agreement, and the requirements set forth in paragraph (c)(1) of this section.





(4) Program, as defined in §2.11, includes an employee of, or provider of medical services under the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section.

(5) If a disclosure to an individual or entity is authorized under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section, the individual or entity may further disclose the patient identifying information that is received for such purposes to its contractor(s), subcontractor(s), or legal representative(s), to carry out the audit or evaluation, and a quality improvement organization which obtains such information under paragraph (a) or (b) of this section may disclose the information to that individual or entity (or, to such individual's or entity's contractors, subcontractors, or legal representatives, but only for the purposes of this section).

(6) The provisions of this paragraph do not authorize the part 2 program, the federal, state, or local government agency, or any other individual or entity to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation as specified in paragraph (c) of this section.

(d) Limitations on disclosure and use. Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the part 2 program or other lawful holder from which it was obtained and may be used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under §2.66.

42 C.F.R. § 2.61 (2020), LEGAL EFFECT OF ORDER.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290dd-2 and the regulations in this part. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under the regulations in this part.

(b) *Examples.*

(1) A person holding records subject to the regulations in this part receives a subpoena for those records. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under the regulations in this part.

(2) An authorizing court order is entered under the regulations in this part, but the person holding the records does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person holding the



records must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of the regulations in this part.

42 C.F.R. § 2.62 (2020), ORDER NOT APPLICABLE TO RECORDS DISCLOSED WITHOUT CONSENT TO RESEARCHERS, AUDITORS AND EVALUATORS.

A court order under the regulations in this part may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under §2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

42 C.F.R. § 2.63 (2020), CONFIDENTIAL COMMUNICATIONS.

(a) A court order under the regulations in this part may authorize disclosure of confidential communications made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment only if:

- (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;
- (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
- (3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

42 C.F.R. § 2.64 (2020), PROCEDURES AND CRITERIA FOR ORDERS AUTHORIZING DISCLOSURES FOR NONCRIMINAL PURPOSES.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which the applicant asserts that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given written consent (meeting the

requirements of the regulations in this part) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be provided:

- (1) Adequate notice in a manner which does not disclose patient identifying information to other persons; and
- (2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order as described in §2.64(d).

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a manner which meets the written consent requirements of the regulations in this part. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

- (1) Other ways of obtaining the information are not available or would not be effective; and
- (2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

- (1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;
- (2) Limit disclosure to those persons whose need for information is the basis for the order; and
- (3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

42 C.F.R. § 2.65 (2020), PROCEDURES AND CRITERIA FOR ORDERS AUTHORIZING DISCLOSURES AND USE OF RECORDS TO CRIMINALLY INVESTIGATE OR PROSECUTE PATIENTS.

(a) *Application.* An order authorizing the disclosure or use of patient records to investigate or prosecute a patient in connection with a criminal proceeding may be applied for by the person holding the records or by any law enforcement or prosecutorial officials who are responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under §2.66 is sought in addition to an order under this section, the person holding the records must be provided:

- (1) Adequate notice (in a manner which will not disclose patient identifying information to other persons) of an application by a law enforcement agency or official;
- (2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order as described in §2.65(d); and
- (3) An opportunity to be represented by counsel independent of counsel for an applicant who is a law enforcement agency or official.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

- (1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.
- (2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.
- (3) Other ways of obtaining the information are not available or would not be effective.
- (4) The potential injury to the patient, to the physician-patient relationship and to the ability of the part 2 program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a law enforcement agency or official, that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within federal, state, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of the extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

42 C.F.R. § 2.66 (2020), PROCEDURES AND CRITERIA FOR ORDERS AUTHORIZING DISCLOSURES AND USE OF RECORDS TO INVESTIGATE OR PROSECUTE A PART 2 PROGRAM OR THE PERSON HOLDING THE RECORDS.

(a) *Application.*

(1) An order authorizing the disclosure or use of patient records to investigate or prosecute a part 2 program or the person holding the records (or employees or agents of that part 2 program or person holding the records) in connection with a criminal or administrative matter may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a part 2 program or the person holding the records (or agents or employees of the part 2 program or person holding the records) in which the applicant asserts that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has provided written consent (meeting the requirements of §2.31) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the part 2 program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order in accordance with §2.66(c).

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of §2.64.

(d) *Limitations on disclosure and use of patient identifying information.*

(1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient in connection with a criminal matter, or be used as the basis for an application for an order under §2.65.

42 C.F.R. § 2.67 (2020), ORDERS AUTHORIZING THE USE OF UNDERCOVER AGENTS AND INFORMANTS TO INVESTIGATE EMPLOYEES OR AGENTS OF A PART 2 PROGRAM IN CONNECTION WITH A CRIMINAL MATTER.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a part 2 program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the part 2 program are engaged in criminal misconduct.

(b) *Notice.* The part 2 program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order in accordance with §2.67(c)), unless the application asserts that:

(1) The part 2 program director is involved in the suspected criminal activities to be investigated by the undercover agent or informant; or

(2) The part 2 program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents of the program who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find all of the following:



- (1) There is reason to believe that an employee or agent of the part 2 program is engaged in criminal activity;
- (2) Other ways of obtaining evidence of the suspected criminal activity are not available or would not be effective; and
- (3) The public interest and need for the placement of an undercover agent or informant in the part 2 program outweigh the potential injury to patients of the part 2 program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a part 2 program must:

- (1) Specifically authorize the placement of an undercover agent or an informant;
- (2) Limit the total period of the placement to six months;
- (3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to investigate or prosecute employees or agents of the part 2 program in connection with the suspected criminal activity; and
- (4) Include any other measures which are appropriate to limit any potential disruption of the part 2 program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed in a part 2 program under this section may be used to investigate or prosecute any patient in connection with a criminal matter or as the basis for an application for an order under §2.65.

45 C.F.R. § 164.506 (2002), USES AND DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) through (4) or that are prohibited under § 164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.*



(1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) Implementation specifications: Treatment, payment, or health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

45 C.F.R. § 164.510 (2002), USES AND DISCLOSURES REQUIRING AN OPPORTUNITY FOR THE INDIVIDUAL TO AGREE OR TO OBJECT.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) Standard: Use and disclosure for facility directories -



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(1) Permitted uses and disclosure. Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Use or disclose for directory purposes such information:

(A) To members of the clergy; or

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) Opportunity to object. A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) Emergency circumstances.

(i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.





(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) Standard: Uses and disclosures for involvement in the individual's care and notification purposes -

(1) Permitted uses and disclosures.

(i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

(2) Uses and disclosures with the individual present. If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) Limited uses and disclosures when the individual is not present. If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person



to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) Uses and disclosures for disaster relief purposes. A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) Uses and disclosures when the individual is deceased. If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT, PUB. L. NO 116-136, § 3221, 134 STAT 281 (Mar. 27, 2020).

(a) CONFORMING CHANGES RELATING TO SUBSTANCE USE DISORDER.—Subsections (a) and (h) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) are each amended by striking “substance abuse” and inserting “substance use disorder”.

(b) DISCLOSURES TO COVERED ENTITIES CONSISTENT WITH HIPAA.—Paragraph (1) of section 543(b) of the Public Health Service Act (42 U.S.C. 290dd–2(b)) is amended to read as follows:

“(1) CONSENT.—The following shall apply with respect to the contents of any record referred to in subsection (a):

“(A) Such contents may be used or disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained.

“(B) Once prior written consent of the patient has been obtained, such contents may be used or disclosed by a covered entity, business associate, or a program subject to this section for purposes of treatment, payment, and health care operations as permitted by the HIPAA regulations. Any information so disclosed may then be redisclosed in accordance with the HIPAA regulations. Section 13405(c) of the Health Information Technology and Clinical Health Act (42 U.S.C. 17935(c)) shall apply to all disclosures pursuant to subsection (b)(1) of this section.



“(C) It shall be permissible for a patient’s prior written consent to be given once for all such future uses or disclosures for purposes of treatment, payment, and health care operations, until such time as the patient revokes such consent in writing.

“(D) Section 13405(a) of the Health Information Technology and Clinical Health Act (42 U.S.C. 17935(a)) shall apply to all disclosures pursuant to subsection (b)(1) of this section.”.

(c) DISCLOSURES OF DE-IDENTIFIED HEALTH INFORMATION TO PUBLIC HEALTH AUTHORITIES.—Paragraph (2) of section 543(b) of the Public Health Service Act (42 U.S.C. 290dd–2(b)), is amended by adding at the end the following:

“(D) To a public health authority, so long as such content meets the standards established in section 164.514(b) of title 45, Code of Federal Regulations (or successor regulations) for creating de- identified information.”.

(d) DEFINITIONS.—Section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended by adding at the end the following:

“(k) DEFINITIONS.—For purposes of this section:

“(1) BREACH.—The term ‘breach’ has the meaning given such term for purposes of the HIPAA regulations.

“(2) BUSINESS ASSOCIATE.—The term ‘business associate’ has the meaning given such term for purposes of the HIPAA regulations.

“(3) COVERED ENTITY.—The term ‘covered entity’ has the meaning given such term for purposes of the HIPAA regulations.

“(4) HEALTH CARE OPERATIONS.—The term ‘health care operations’ has the meaning given such term for purposes of the HIPAA regulations.

“(5) HIPAA REGULATIONS.—The term ‘HIPAA regulations’ has the meaning given such term for purposes of parts 160 and 164 of title 45, Code of Federal Regulations.

“(6) PAYMENT.—The term ‘payment’ has the meaning given such term for purposes of the HIPAA regulations.

“(7) PUBLIC HEALTH AUTHORITY.—The term ‘public health authority’ has the meaning given such term for purposes of the HIPAA regulations.





“(8) TREATMENT.—The term ‘treatment’ has the meaning given such term for purposes of the HIPAA regulations.

“(9) UNSECURED PROTECTED HEALTH INFORMATION.—The term ‘unprotected health information’ has the meaning given such term for purposes of the HIPAA regulations.”.

(e) USE OF RECORDS IN CRIMINAL, CIVIL, OR ADMINISTRATIVE INVESTIGATIONS, ACTIONS, OR PROCEEDINGS.— Subsection (c) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2(c)) is amended to read as follows:

“(c) USE OF RECORDS IN CRIMINAL, CIVIL, OR ADMINISTRATIVE CONTEXTS.—Except as otherwise authorized by a court order under subsection (b)(2)(C) or by the consent of the patient, a record referred to in subsection (a), or testimony relaying the information contained therein, may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority, against a patient, including with respect to the following activities:

“(1) Such record or testimony shall not be entered into evidence in any criminal prosecution or civil action before a Federal or State court.

“(2) Such record or testimony shall not form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency.

“(3) Such record or testimony shall not be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation.

“(4) Such record or testimony shall not be used in any application for a warrant.”.

(f) PENALTIES.—Subsection (f) of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended to read as follows:

“(f) PENALTIES.—The provisions of sections 1176 and 1177 of the Social Security Act shall apply to a violation of this section to the extent and in the same manner as such provisions apply to a violation of part C of title XI of such Act. In applying the previous sentence—

“(1) the reference to ‘this subsection’ in subsection (a)(2) of such section 1176 shall be treated as a reference to ‘this subsection (including as applied pursuant to section 543(f) of the Public Health Service Act)’; and

“(2) in subsection (b) of such section 1176—





“(A) each reference to ‘a penalty imposed under subsection (a)’ shall be treated as a reference to ‘a penalty imposed under subsection (a) (including as applied pursuant to section 543(f) of the Public Health Service Act)’; and

“(B) each reference to ‘no damages obtained under subsection (d)’ shall be treated as a reference to ‘no damages obtained under subsection (d) (including as applied pursuant to section 543(f) of the Public Health Service Act)’.”.

(g) ANTIDISCRIMINATION.—Section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) is amended by inserting after subsection (h) the following:

“(i) ANTIDISCRIMINATION.—

“(1) IN GENERAL.—No entity shall discriminate against an individual on the basis of information received by such entity pursuant to an inadvertent or intentional disclosure of records, or information contained in records, described in subsection (a) in—

“(A) admission, access to, or treatment for health care;

“(B) hiring, firing, or terms of employment, or receipt of worker’s compensation; “(C)

the sale, rental, or continued rental of housing;

“(D) access to Federal, State, or local courts; or

“(E) access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.

“(2) RECIPIENTS OF FEDERAL FUNDS.—No recipient of Federal funds shall discriminate against an individual on the basis of information received by such recipient pursuant to an intentional or inadvertent disclosure of such records or information contained in records described in subsection (a) in affording access to the services provided with such funds.”.

(h) NOTIFICATION IN CASE OF BREACH.—Section 543 of the Public Health Service Act (42 U.S.C. 290dd–2), as amended by subsection (g), is further amended by inserting after subsection (i) the following:

“(j) NOTIFICATION IN CASE OF BREACH.—The provisions of section 13402 of the HITECH Act (42 U.S.C. 17932) shall apply to a program or activity described in subsection (a), in case of a breach of records described in subsection (a), to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.”.

(i) REGULATIONS.—





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(1) **IN GENERAL.**—The Secretary of Health and Human Services, in consultation with appropriate Federal agencies, shall make such revisions to regulations as may be necessary for implementing and enforcing the amendments made by this section, such that such amendments shall apply with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of this Act.

(2) **EASILY UNDERSTANDABLE NOTICE OF PRIVACY PRACTICES.**—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate legal, clinical, privacy, and civil rights experts, shall update section 164.520 of title 45, Code of Federal Regulations, so that covered entities and entities creating or maintaining the records described in subsection (a) provide notice, written in plain language, of privacy practices regarding patient records referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)), including—

(A) a statement of the patient’s rights, including self-pay patients, with respect to protected health information and a brief description of how the individual may exercise these rights (as required by subsection (b)(1)(iv) of such section 164.520); and

(B) a description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient’s written authorization (as required by subsection (b)(2) of such section 164.520).

(j) **RULES OF CONSTRUCTION.**—Nothing in this Act or the amendments made by this Act shall be construed to limit—

(1) a patient’s right, as described in section 164.522 of title 45, Code of Federal Regulations, or any successor regulation, to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) for purposes of treatment, payment, or health care operations; or

(2) a covered entity’s choice, as described in section 164.506 of title 45, Code of Federal Regulations, or any successor regulation, to obtain the consent of the individual to use or disclose a record referred to in such section 543(a) to carry out treatment, payment, or health care operation.

(k) **SENSE OF CONGRESS.**—It is the sense of the Congress that—

(1) any person treating a patient through a program or activity with respect to which the confidentiality requirements of section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) apply is encouraged to access the applicable State-based prescription drug monitoring program when clinically appropriate;



- (2) patients have the right to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) for treatment, payment, or health care operations;
- (3) covered entities should make every reasonable effort to the extent feasible to comply with a patient’s request for a restriction regarding such use or disclosure;
- (4) for purposes of applying section 164.501 of title 45, Code of Federal Regulations, the definition of health care operations shall have the meaning given such term in such section, except that clause (v) of paragraph (6) shall not apply; and
- (5) programs creating records referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) should receive positive incentives for discussing with their patients the benefits to consenting to share such records.

CRIMINAL JUSTICE STANDARDS FOR THE PROSECUTION FUNCTION § 3-1.11(c) (AM. BAR ASS’N 2017).

(c) In creating or participating in any literary or other media account of a matter in which the prosecutor was involved, the prosecutor’s duty of confidentiality must be respected even after government service is concluded. When protected confidences are involved, a prosecutor or former prosecutor should not make disclosure without consent from the prosecutor’s office. Such consent should not be unreasonably withheld, and the public’s interest in accurate historical accounts of significant events after a lengthy passage of time should be considered.

CRIMINAL JUSTICE STANDARDS FOR THE PROSECUTION FUNCTION § 3-3.4(k) (AM. BAR ASS’N 2017).

(k) Subject to ethical rules and the confidentiality that criminal matters sometimes require, and unless prohibited by law or court order, the prosecutor should information about the status of matters in which they are involved to victims and witnesses who request it.

MODEL RULES OF PROF’L CONDUCT R. 1.6 (AM. BAR ASS’N 2020).

(a) A lawyer shall not reveal information relating to the representation of a client unless the client gives informed consent, the disclosure is impliedly authorized in order to carry out the representation or the disclosure is permitted by paragraph (b).

(b) A lawyer may reveal information relating to the representation of a client to the extent the lawyer reasonably believes necessary:

- (1) to prevent reasonably certain death or substantial bodily harm;
 - (2) to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer's services;
 - (3) to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the lawyer's services;
 - (4) to secure legal advice about the lawyer's compliance with these Rules;
 - (5) to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client;
 - (6) to comply with other law or a court order; or
 - (7) to detect and resolve conflicts of interest arising from the lawyer's change of employment or from changes in the composition or ownership of a firm, but only if the revealed information would not compromise the attorney-client privilege or otherwise prejudice the client.
- (c) A lawyer shall make reasonable efforts to prevent the inadvertent or unauthorized disclosure of, or unauthorized access to, information relating to the representation of a client.

NAT'L PROSECUTION STANDARDS § 2-9.1 (NAT'L DIST. ATTORNEYS ASSOC. 2009).

Victims of violent crimes, serious felonies, or any actions where it is likely the victim may be the object of physical or other forms of retaliation should be informed of all important stages of the criminal justice proceedings to the extent feasible, upon request or if required by law, including, but not limited to, the following:

- a. Acceptance or rejection of a case by the prosecutor's office, the return of an indictment, or the filing of criminal charges;
- b. A determination of pre-trial release of the defendant;
- c. Any pre-trial disposition;
- d. The date and results of trial;

- e. The date and results of sentencing;
- f. Any proceeding within the knowledge of the prosecutor which does or may result in the defendant no longer being incarcerated, including appellate reversal, parole, release, and escape, unless a legal obligation to inform the victim of such proceeding is imposed by law on another governmental entity; and
- g. Any other event within the knowledge of the prosecutor that may put the victim at risk of harm or harassment.

NAT'L PROSECUTION STANDARDS § 2-9.4 (NAT'L DIST. ATTORNEYS ASSOC. 2009).

The prosecutor should work with other law enforcement agencies to:

- a. Cooperate with victim advocates for the benefit of providing direct and referral services to victims of crime; and
- b. Assist in the protection of a victim's right to privacy regarding a victim's Social Security number, birth date, address, telephone number, place of employment, name (when the victim is a minor or a victim of sexual assault,) or any other personal information unless either a court finds it necessary to that proceeding or disclosure is required by law.

WISCONSIN'S RULES OF PROF'L CONDUCT FOR ATTORNEYS, S.C.R., Ch. 20, R. 1.6 (2020).

- (a) A lawyer shall not reveal information relating to the representation of a client unless the client gives informed consent, except for disclosures that are impliedly authorized in order to carry out the representation, and except as stated in pars. (b) and (c).
- (b) A lawyer shall reveal information relating to the representation of a client to the extent the lawyer reasonably believes necessary to prevent the client from committing a criminal or fraudulent act that the lawyer reasonably believes is likely to result in death or substantial bodily harm or in substantial injury to the financial interest or property of another.
- (c) A lawyer may reveal information relating to the representation of a client to the extent the lawyer reasonably believes necessary:
 - (1) to prevent reasonably likely death or substantial bodily harm;



(2) to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the lawyer's services;

(3) to secure legal advice about the lawyer's conduct under these rules;

(4) to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client;

(5) to comply with other law or a court order; or

(6) to detect and resolve conflicts of interest, but only if the revealed information would not compromise the attorney-client privilege or otherwise prejudice the client.

(d) A lawyer shall make reasonable efforts to prevent the inadvertent or unauthorized disclosure of, or unauthorized access to, information relating to the representation of a client.

Case Law

United States v. Eide, 875 F.3d 1429 (1989).

Defendant Stephen Eide was a pharmacist at the Veteran Administration Medical Center (VAMC). After being found in his car with needles, syringes and drugs by two police officers, Eide informed the officers that he had injected himself with drugs. Eide was taken to VAMC's emergency room where he admitted to his drug use and consented to a urinalysis which revealed the presence of methadone, morphine and Darvon. Although Eide was under the influence of drugs, disoriented and mildly confused, he was coherent, knew where he was and could understand and respond to questions. A week later, an audit at the VAMC pharmacy revealed that someone had tampered with methadone, morphine and cocaine. The FBI was called and the agents were told by VAMC staff that Eide was a suspect and were given the results of Eide's urinalysis as well as letter from doctors containing Eide's admissions in the emergency room. When the FBI went to Eide's residence and after telling Eide that they had his urinalysis results, Eide admitted to the tampering. The court holds that the urinalysis results and Eide's admissions to his doctors should have been suppressed because he was protected under Part 2.

United States v. White, 902 F. Supp. 1347, 1352 (D. Kan. 1995).



Defendant White was convicted of drunk driving. Prior to sentencing, White was evaluated by a mental health center, where White disclosed information indicating a history of substance abuse. White was then sentenced to serve a one-year term of probation conditioned upon her serving 72 hours in jail, paying a fine, and completing a substance abuse treatment program. She was required to disclose her conviction and her history of substance abuse to the county's health department, and social and rehabilitation services to facilitate White's participation and completion of the substance abuse treatment program. White contends that the portion of the sentence requiring her to disclose her history of substance violated Part 2. The court holds that § 2.35 applies to the case because the information concerning defendant's substance abuse history will be disclosed in connection with the judge's performance of his official duties of pronouncing and imposing sentence.

This project was supported by Grant No. 2017-YX-BX-K002 awarded by the Bureau of Justice Assistance. The Bureau of Justice Assistance is a component of the Department of Justice's Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and the SMART Office. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice