

**A PROPOSAL TO PROMOTE COORDINATION OF CARE AND TO STRENGTHEN PATIENT PROTECTIONS
UNDER THE FEDERAL ALCOHOL AND DRUG ABUSE CONFIDENTIALITY LAW**

PREPARED FOR THE PATIENT PROTECTION COALITION

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INTRODUCTION

The Federal Confidentiality of Alcohol and Drug Abuse Patient Records law reflects Congress' longstanding concern that individuals not be made more vulnerable as a result of seeking treatment for a substance use disorder. Concerns about stigma and discrimination against people who receive substance use disorder treatment are as real now as they were when the statute was enacted in 1972. It remains important to take exceptional care to protect the privacy of people who seek treatment for addictions.

Yet the nation's health delivery system has changed, and there is a national interest in promoting the coordination of health services delivered by multiple providers and in implementation of electronic health records.

Under the current statutory and regulatory framework, physicians and case managers cannot access any information about an individual's substance use disorder treatment covered by the 1972 federal confidentiality law without specific written authorization, except in cases of emergency. This creates communication barriers that limit the ability of health care providers and health plans to identify and conduct outreach to people who may be receiving duplicative or inappropriate treatment and coordinate care of persons who may be at significant risk. This directly impacts patient care and safety.

The following proposal balances the need to facilitate communications in support of the delivery of coordinated health care with the need to protect the privacy interests of persons who seek treatment from substance use disorder treatment programs.

It permits very limited disclosures of information about substance use disorder treatment to health care providers and health plans for purposes of treatment, coordination of care, recovery support, quality improvement, disease management and payment. Disclosures allowed by the proposal are much more restricted than those allowed by the HIPAA Privacy Rule. Further, the only items that can be disclosed without authorization for these two limited exceptions are demographic information, diagnosis, medications, laboratory results, and identification of past or current treatment providers.

Recognizing that even these limited disclosures could create a risk of improper use of the information and that the current statute is silent on a number of necessary patient protections, the proposal also includes robust provisions to address these fundamental vulnerabilities. Specifically, the proposal includes enhancements that: (1) prohibit discrimination on the basis of information in substance use disorder program records, (2) limit use in criminal and civil investigations or proceedings, (3) strengthen civil and criminal sanctions against unauthorized disclosures, and (4) give individuals the right to pursue civil remedies against persons who violate this statute.

In sum, the proposal couples a modest, but necessary, liberalization of treatment-related disclosure with several major amendments designed to strengthen the Act's sanctions and remedies for breaches of confidentiality. The proposal and accompanying commentary are set forth below. The language that would be added to the statute is underlined. Language that would be deleted is shown with a strike through it.

This proposal was prepared by a committee of attorneys who are highly experienced in the law governing operation of behavioral health service systems, privacy, and health information technology. The committee was chaired by Professor Richard J. Bonnie of the University of Virginia School of Law, and includes Jalena Bingham, Paul Litwak, Renée Popovits and Kelly Whelan. Eric Goplerud, Ph.D. of George Washington University guided the work of the committee. Comments and feedback are welcome. They can be provided to Dr. Goplerud at (202) 994-4303, goplerud@gwu.edu, or to Professor Bonnie at rbonnie@virginia.edu.

| 42 USC 290dd-2 | Purposes of Proposed Amendment |
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| <p>(a) Requirement</p> <p>Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.</p> <p>(b) Permitted disclosure</p> <p>(1) Consent</p> <p>The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) (i) of this section.</p> <p>(2) Method for disclosure</p> <p>Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives written consent, the content of such record may be disclosed as follows:</p> <p>(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.</p> <p>(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.</p> <p>(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.</p> | |

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| <p><u>(D) To and among health care providers and health plans for purposes of providing or coordinating health care and related services, or implementing recovery support services, or quality improvement or disease management programs with respect to the individual who is the subject of the record referred to in subsection (a).</u></p> | <p><i>New subsection (b)(2)(D) permits health care providers and health plans to share limited information for the specific purposes of providing or coordinating health care and related services, or implementing recovery support services, or quality improvement or disease management protocols.</i></p> <p><i>This is consistent with current efforts to reform the health system, facilitate electronic health record exchange and promote development of coordinated systems of care.</i></p> <p><i>It is simply impractical to require individual approval of each of these limited disclosures of substance use disorder program information. Efforts by primary care physicians and case managers to coordinate physical health, mental health, prescription drug and substance use disorder treatment of high-risk individuals are effectively crippled by the consent requirements of the current statute and regulations.</i></p> <p><i>The amount of information that may be disclosed for this purpose without consent is limited by subsection (b)(3)(B), below. Recipients are not permitted to use or disclose the information received for purposes that are not permitted by the statute and regulations.</i></p> |
| <p><u>(E) To health plans for payment purposes, subject to the prohibition against discrimination set forth in subsection (f) of this section.</u></p> | <p><i>New subsection (b)(2)(E) permits disclosures for payment purposes without the written consent of the patient. Section (f) is added by this proposal. It prohibits use of a substance use program record by a health plan for discriminatory purposes.</i></p> <p><i>Please note that section 13405(a) of the HITECH Act requires HIPAA covered entities and business associates to honor an individual's request to restrict disclosure to a health plan if payment for services is made out of pocket. This provision applies to substance use disorder programs.</i></p> <p><i>While this proposal eliminates the existing requirement of consent for disclosures for payment purposes, subsection (b)(3)(B) narrows the set of information that may be disclosed for that purpose.</i></p> |

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| <p><u>(3) Minimum Necessary Standard.</u></p> <p><u>(A) Generally.</u> Except as authorized by a court order granted under subsection (b)(2)(C) of this section, the use, disclosure or request for the content of a record shall, to the extent practicable, be limited to the minimum necessary to accomplish the intended purpose of such, use, disclosure or request, respectively. For purposes of compliance with this provision, the “minimum necessary” shall be based upon guidance issued by the Secretary in accordance with section 13405 (b)(1)(B) of the American Recovery and Reinvestment Act of 2009.</p> <p><u>(B) Limitations on Content of Certain Disclosures.</u> Disclosures made pursuant to subsections (b)(2)(D) and (b)(2)(E) of this section shall be limited to demographic information, diagnosis, medications, laboratory results, and identification of past or current treatment providers. Such disclosures may not include progress notes, psychotherapy notes (as defined by the Secretary in title 45, Code of Federal Regulations, Parts 160-164) or records for which disclosure may be restricted as provided in section 13405(a) of the American Recovery and Reinvestment Act of 2009.</p> | <p><i>Subsection (b)(3)(A) adds a “minimum necessary” standard that will apply to <u>any</u> disclosure of alcohol/drug program patient records. This is modeled after language limiting uses and disclosures of protected health information set forth in the HIPAA Privacy Rule and the HITECH Act. Addition of this requirement is significant in light of the enforcement provisions that follow.</i></p> <p><i>Subsection (b)(3)(B) limits the scope of the information that may be disclosed without patient consent under new subsections (b)(2)(D) and (b)(2)(E). This information is limited to that required to provide a physician or care manager a high level view of all of the services an individual is receiving. Psychotherapy notes and progress notes are specifically excluded. If the recipient requires more detailed information about a person’s substance use treatment, written consent will be required (except in emergencies).</i></p> <p><i>Please note that individuals who receive substance use disorder services retain the right to request restrictions on uses and disclosures of protected health information that was created by the HIPAA Privacy Rule at 45 CFR 164.522.</i></p> <p><i>Establishment of a clear and consistently accepted set of rules that associate specific data elements and disclosure authorization requirements is essential to creation of interoperability standards for electronic health records for behavioral health systems. By defining those data elements, the permitted recipients of data, and the permitted purposes of disclosure, this proposal advances the public policy of promotion of development and use of secure interoperable electronic health records.</i></p> |
| <p><u>(4) Restrictions on Re-disclosure of Records.</u></p> <p><u>A recipient of any record described in subsection (a) of this section may only use or re-disclose such records as permitted by this section and regulations issued by the Secretary pursuant to subsection (i).</u></p> | <p><i>Subsection (b)(4) adds to the statute a prohibition against re-disclosure of alcohol/drug program records for purposes that are not permitted by the statute or implementing regulations. This prevents a recipient of a record from re-disclosing information in the record for purposes that might be permitted by HIPAA but prohibited by this statute or by 42 CFR Part 2.</i></p> |

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| <p>(c) Use of records in criminal <u>legal</u> proceedings</p> <p>Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used <u>(i) to initiate or substantiate any criminal charges against a patient person who is the subject of the record, or (ii) to conduct any investigation of a patient person who is the subject of the record or (iii) as evidence against the person who is the subject of the record in any proceeding brought by the government.</u></p> | <p><i>To further minimize patient fears of being arrested and prosecuted or suffering loss or discrimination in a civil proceeding, the drafters expanded the existing provision pertaining to criminal proceedings. The intent of this provision is to override case law that limits privacy rights by permitting the use of confidential alcohol/drug treatment information in evidence in government proceedings against the patient without a court order that meets the requirements of section (b)(2)(C).</i></p> |
| <p>(d) Application</p> <p>The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.</p> <p>(e) Nonapplicability</p> <p>The prohibitions of this section do not apply to any interchange of records—</p> <p>(1) within the Uniformed Services or within those components of the Department of Veterans Affairs furnishing health care to veterans; or</p> <p>(2) between such components and the Uniformed Services.</p> <p>The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.</p> | |

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| <p><u>(f) Nondiscrimination</u></p> <p><u>(1) Discrimination in Health Coverage</u></p> <p><u>It shall be unlawful for any health plan or health insurance program to use records described in subsection (a) of this section to deny or condition the issuance or effectiveness of a plan, policy or coverage (including the imposition of any exclusion of benefits under the plan, policy, or coverage based on a preexisting condition) or to discriminate in the pricing of the plan, policy or coverage (including adjusting the premium rates) of an individual on the basis of the contents of such records.</u></p> <p><u>(2) Discrimination in Provision of Health Care Services</u></p> <p><u>It shall be unlawful for any health care provider to deny access to or discriminate in the provision of medically necessary health care services to an individual who is the subject of a record described in subsection (a) on the basis of the contents of such record. Nothing in this subsection is intended to require a health care provider to deliver a service which is clinically inappropriate or which the health care provider does not ordinarily provide to the general public. Nor is anything in this section intended to prevent a substance abuse recovery program, residential program, or other program from conditioning access to and continuing participation in the program on maintenance of sobriety or non-possession of alcohol or drugs.</u></p> | <p><i>Prevention of stigma and discrimination against people who seek treatment for alcohol or drug addictions was a primary concern that led to enactment of this confidentiality statute. Yet, the current statute is silent on these issues and provides no protections to address these fundamental vulnerabilities. The language set forth in new subsection (f)(1) is modeled after anti-discrimination provisions set forth in the Genetic Information Nondiscrimination Act of 2008 (GINA). The intent of subsections (f)(1) and (f)(2) is to explicitly address and close the gap in the statutory framework by expressly prohibiting discrimination based on the content of substance use treatment records. It is contemplated that these subsections, in conjunction with the expanded enforcement mechanism described below, will provide meaningful protections that the current statutory and regulatory scheme regrettably lacks.</i></p> |

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| <p>(f) (g) Penalties</p> <p>(1) Application of Title 18</p> <p>Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18.</p> <p>(2) Application of HIPAA Penalties</p> <p><u>The provisions of sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d-5, 1320d-6) shall apply to any person with respect to the violation of this section in the same manner as such provisions apply to a person who violates a provision of part C of title XI of such Act. The Secretary shall be empowered to investigate violations of this section and impose civil penalties as provided in section 1176 of the Social Security Act (42 U.S.C. 1320d-5) and regulations issued by the Secretary thereunder.</u></p> | <p><i>Remedies for violation of the privacy rights of substance use disorder patients are limited, and poorly enforced. The proposed revisions to subsection (g) and the new subsection (h) are intended to create a comprehensive, meaningful enforcement mechanism for violations of the statute.</i></p> <p><i>New subsection (g)(2) applies the civil and criminal penalties for violation of the HIPAA Rules and the HITECH Act to violations of the substance use disorder privacy law and regulations. The HITECH Act significantly increased these penalties and applied them to HIPAA covered entities and their business associates. This new provision applies not just to substance use programs and health plans, which are already covered by the HIPAA rules, but to any recipient of confidential substance use program information. It also applies the HIPAA/HITECH penalties when a disclosure is unlawful under 42 USC 290dd-2 and 42 CFR Part 2, but lawful under HIPAA.</i></p> |

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| <p><u>(h) Private Right of Action</u></p> <p><u>(1) Right to Bring Civil Action</u></p> <p><u>An individual who is the subject of a record described in subsection (a) may bring a civil action in the United States District Court against a person that uses or discloses the contents of such record in a manner that is prohibited by this section or any rule promulgated by the Secretary in accordance with subsection (i) hereunder. The United States District Court shall have jurisdiction over any such action regardless of the amount in controversy and without regard to diversity jurisdiction. An action pursuant to this subsection shall be commenced within two years of discovery of the prohibited use or disclosure of the contents of the record.</u></p> <p><u>(2) Remedies</u></p> <p><u>(A) In any suit brought under the provisions of subsection (h)(1), the Court may issue a temporary restraining order or injunction to prevent further violations of this section.</u></p> <p><u>(B) In any suit brought under the provisions of subsection (h)(1), the Court shall award to each individual complainant who prevails in such action:</u></p> <p><u>(i) Actual damages sustained by the individual, including damages for mental suffering;</u></p> <p><u>(ii) The costs of the action together with reasonable attorney's fees as determined by the court; and</u></p> <p><u>(iii) In addition to any special or general damages, a minimum of two thousand five hundred dollars (\$2,500) in exemplary damages shall be awarded to each complainant if the Court finds that the unauthorized use or disclosure was the result of willful, knowing, or reckless actions by the defendant.</u></p> <p><u>(3) Non-Exclusive Rights</u></p> <p><u>The rights and remedies set forth in this section shall be deemed to be nonexclusive and are in addition to all those rights and remedies which are otherwise available under any other provision of state or federal law.</u></p> | <p><i>This section gives individuals whose records are unlawfully used or disclosed the right to bring a civil action in federal court to obtain an injunction and/or monetary damages. It requires payment of costs, including attorney's fees to a patient that prevails in such a case. If an unauthorized use or disclosure was the result of willful, knowing or reckless actions, exemplary damages are required.</i></p> <p><i>This section gives substance use disorder program patients a right of enforcement that is not available under HIPAA or the HITECH Act.</i></p> <p><i>The draft language is derived from California law that gives similar rights to persons whose personal information is unlawfully disclosed.</i></p> |

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| <p>(g) (i) Regulations</p> <p>Except as provided in subsection (h) (i) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations <u>shall be issued no later than 12-months following enactment of this section.</u> Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.</p> | <p><i>The drafters believe the important protections afforded by these revisions to the statute should be incorporated into regulations no later than 1-year after the revised statute is passed. This mandated revision of 42 CFR Part 2 provides an opportunity for DHHS to update the rule to reflect legal and technical changes that have occurred since 42 CFR Part 2 was first enacted, including the enactment of HIPAA and the HITECH Act and the creation of electronic health records.</i></p> |
| <p>(h) (i) Application to Department of Veterans Affairs</p> | |
| <p>The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, prescribe regulations making applicable the regulations prescribed by the Secretary of Health and Human Services under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.</p> | |