



NEW YORK STATE OFFICE OF MENTAL HEALTH

HIPAA PRIVACY RULE PREEMPTION ANALYSIS

Prepared by the Office of Counsel
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Deputy Commission and Counsel

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Associate Counsel

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August 28, 2002

Dear Reader:

Thank you for your interest in the New York State Office of Mental Health HIPAA Preemption Analysis. Please be advised that this document is intended for internal use by the Office of Mental Health and its employees, and is not intended to serve as legal advice to anyone outside this Office. While we are hopeful that it will provide you with general guidance, please consult your own attorney for specific legal advice concerning your own HIPAA compliance.

As noted in Introduction, please do not further distribute this document without our express permission. We welcome your comments and feedback, and thank you again for your interest.

Sincerely,

JulieAnne Rodak
Associate Counsel

AN EQUAL OPPORTUNITY/AFFIRMATIVE ACTION EMPLOYER

OMH 26.05 (11-95)

NEW YORK STATE OFFICE OF MENTAL HEALTH

Health Care Portability and Accountability Act (HIPAA)

Preemption Analysis

The New York State Office of Mental Health HIPAA Preemption Analysis is designed to examine the interplay between the HIPAA Privacy Regulations (45 CFR Parts 160 and 164) and a variety of New York State statutes, regulations, and other precedent most commonly referred to when using and disclosing mental health treatment information. Readers are cautioned that while comprehensive in scope, the Analysis does not represent a complete overview of all legal precedent that may impact such uses and disclosures, but it does attempt to address those most often utilized. Furthermore, this Analysis is not intended to substitute as legal advice, and readers are urged to consult with their attorneys when developing HIPAA compliance strategies or if considering specific legal questions.

This Analysis reflects New York State and federal laws and regulations as of August 14, 2002, and does reflect amendments adopted by the Department of Health and Human Services and published on that date. However, as both federal and state law are constantly changing, and the body of knowledge and interpretive guidance around these regulations are continually evolving, this Analysis remains subject to modification by the New York State Office of Mental Health.

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HIPAA Privacy Rule NYS Office of Mental Health Preemption Analysis

Background:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal statute that includes provisions which govern the development of uniform health information data standards and privacy standards. This federal statute will “preempt,” or take precedence over, any contrary state law unless the state law is more stringent than federal law or a specific exception applies. Therefore, in order for entities in New York State to be able to comply with the HIPAA privacy law and regulations, it is necessary to first determine how HIPAA affects New York State laws and rules that govern the privacy of health information.

Scope of Analysis:

This analysis compares various sections of New York State law, most significantly the New York State Mental Hygiene Law, that relate to the use or disclosure of health information. It is not, however, intended to be a comprehensive review of all statutes in New York State that govern the use or disclosure of health information. Instead, it reflects the authority most commonly consulted by providers of mental health services. This analysis also does not examine a variety of other sources that may have the “force and effect” of law and which also require a preemption analysis, such as the NYS Constitution, NYS Attorney General Opinions, or case law. It is important to note that the analysis presented here was drafted for internal use by New York State Office of Mental Health employees, and is intended to provide initial guidance to others undertaking an examination of New York State law.

Comments:

The New York State Office of Mental Health encourages individuals and entities that review this document to provide us with your feedback. There may be instances where others have a differing opinion or interpretation with regard to the application of the laws analyzed here and how they may be affected by HIPAA; if so, we are interested in reviewing your analysis. Please submit your comments in writing to: NYS Office of Mental Health Counsel’s Office; ATTN: HIPAA Preemption Analysis; 44 Holland Avenue; Albany, NY 12229.

Disclaimer:

The information provided here is for reference only and does not constitute the rendering of legal, financial, or other professional advice by the New York State Office of Mental Health. Any links or references in these materials are not endorsements by this Office. Users are cautioned to review and update application and implementation of federal and New York State privacy laws when these laws are amended or new law is created.

**New York State Office of Mental Health
HIPAA Preemption Analysis**

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New York State Office of Mental Health HIPAA Preemption Analysis

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
MHL ARTICLE 7 - OFFICE OF MENTAL HEALTH		
<p>Access to Criminal History Information:</p> <p>MHL §7.09(j): The Commissioner of OMH is authorized to have access to criminal history information contained in the central data facility established by DCJS; summary reports can be included in patient records for purposes of making decisions regarding care and treatment, health and safety, privileges and discharge planning for patients admitted to/retained in hospitals operated by OMH.</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p> <p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption:</u> Assuming DCJS is not a covered entity under HIPAA, there are no HIPAA restrictions on its disclosures to OMH. OMH is authorized to receive criminal justice information by State law.</p>
<p>Directors of Facilities: Subpoena Authority:</p> <p>MHL §7.21 (c): In any investigation into treatment and care of patients or the conduct, performance, or neglect of duty of officers or employees, the director of a department hospital shall be authorized to subpoena witnesses, compel their attendance, administer oaths to witnesses, examine witnesses under oath, and require the production of any books or papers deemed relevant to the inquiry or investigation. A subpoena issued under this section shall be regulated by the civil practice law and rules.</p>	<p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.512(d) A covered entity may disclose PHI to a health oversight agency for oversight activities authorized by law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order.</p>	<p><u>No Preemption.</u> Disclosures to facility directors under these circumstances can be made consistent with the “health oversight agency” and “in the course of administrative proceedings” exceptions to the HIPAA regulations. As such, the State law is not contrary to the Federal regulations and State law applies.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Board of Visitors:</p> <p>MHL §7.33 (h): Any member of the Board of Visitors of an OMH facility may visit and inspect such facility at any timethe board shall have the power to investigate all charges against the director and all cases of alleged patient abuse or mistreatment.....in conducting such an investigation, the board shall have the power, in accordance with the civil practice law and rules, to subpoena witnesses, compel their testimony,.....and require the production of any books or records deemed relevant to the investigation.</p>	<p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d) A covered entity may disclose PHI to a health oversight agency for oversight activities authorized by law.</p>	<p><u>No Preemption.</u> Disclosures to the Board of Visitors can be made consistent with the “health oversight agency” and “required by law” exceptions to the HIPAA regulations. As such, the State law is not contrary to the Federal regulations and State law applies.</p>
<p>Transitional Care:</p> <p>MHL §7.38 (c),(f)</p> <p>(c) The Office shall enter into a memorandum of understanding with the department of social services to facilitate access by the office to child care facilities providing transitional care to young adults as may be necessary by the office to meet its responsibilities for monitoring the care of young adults.</p>	<p><i>re: (c):</i> §164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p><i>re: (f):</i> §164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but</p>	<p><i>re: (c):</i></p> <p><u>No Preemption.</u> Access to PHI by OMH can be obtained consistent with the “health oversight agency” exception to the HIPAA regulations. As such, the State law is not contrary to the Federal regulations and State law applies.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>(f) In any case where an individual receiving transitional funding is about to be transferred from one facility to another, a transfer plan shall be prepared by the sending facility and forwarded to the receiving facility and the individual, and unless the individual objects, parents, guardians or other persons interested in the care of such person prior to the transfer. The transfer plan shall include any information necessary to facilitate a safe transfer, such as specific problems, a schedule for administering medications and behavior unique to the individual.</p>	<p>is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.510(b)(1): A covered entity may disclose to a family member, other relative, close personal friend of the individual or any other person identified by the individual, the PHI directly relevant to such persons involvement with the individual's care or payment related to the individual's care, if the individual is given the opportunity to agree, prohibit, or restrict the disclosure.</p>	<p><i>re: (f):</i> <u>No Preemption:</u> The state law requirement mandating that a transfer plan be submitted from a sending facility to both a receiving facility and the individual is permitted via the "required by law" exception in HIPAA and hence this part of the State law is not preempted. Furthermore, adoption of the proposed amendments to HIPAA, which eliminated the requirement for obtaining patient consent to use/disclose PHI for treatment purposes, render this provision consistent with HIPAA.</p> <p>With regard to notifications of parents, guardians, and other interested persons, the State law provision which affords an opportunity for the patient to object to such notifications is consistent with HIPAA. As such, State law applies.</p>
<p>MHL ARTICLE 9 - HOSPITALIZATION OF MENTALLY ILL</p>		

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Voluntary Admissions:</p> <p>MHL §9.13(b): ...if there are reasonable grounds for belief that the patient may be in need of involuntary care and treatment, the director may retain the need for the patient for a period not to exceed 72 hours... Before the expiration of such 72 hour period, the director shall either release the patient or apply to the supreme court or the county court in the county where the hospital is located for an order authorizing the involuntary retention of such patient.</p>	<p>§164.506(a)(3)(i)(B) :If the covered health care provider is required by law to treat the individual, and the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	<p><u>No preemption:</u> If a person meets the statutory criteria for involuntary treatment, a court will issue an order requiring that such treatment be provided (i.e., the treatment is “required by law.”) Inasmuch as the disclosures necessary to initiate an action to obtain such order must be made, the “treatment required by law” exception can be reasonably be deemed to extend back to the information that forms the foundation of the order</p> <p>Note: Under State law, there is no requirement that an attempt be made to obtain patient consent, which would have required a change in current practice; however 8/02 adoption of amendments removing the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes removes this as a concern.</p>
<p>Voluntary/Informal Admissions; Review of Status:</p> <p>MHL §9.25: ...The director shall review the suitability of such patient to remain in such status, and the mental hygiene legal service shall review the willingness of such patient to remain in such status. Notice of the determination of the patient's suitability made by the director shall be given to the mental hygiene legal service.....</p>	<p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Involuntary Admission on Medical Certification:</p> <p>MHL §9.27(f): Following admission to a hospital, no patient may be sent to another hospital by any form of involuntary admission unless the mental hygiene legal service has been given notice thereof.</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p>
<p>Involuntary Admission on Medical Certification: Notice of Admission to Patients and Others</p> <p>MHL §9.29: (a) The director shall cause written notice of a person's involuntary admission on an application supported by medical certification to be given forthwith to the Mental Hygiene Legal Services. (b) The director shall cause written notice of the admission of such person....after such admission to the following:</p> <ol style="list-style-type: none"> 1. The nearest relative of the person alleged to be mentally ill other than the applicant, if there be any such person known to the director; 2. As many as 3 additional persons, if designated in writing to receive such notice by the person admitted. 	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.510(b)(1): A covered entity may disclose to a family member, other relative, close personal friend of the individual or any other person identified by the individual, the PHI directly relevant to such persons involvement with the individual's care or payment related to the individual's care, if the individual is given the opportunity to agree, prohibit, or restrict the disclosure.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI to the MHLS and the nearest relative of the patient is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law. Further, the ability afforded a patient by State law to designate other persons to receive notice of the patient's hospitalization is consistent with HIPAA provisions that permit such notifications, provided patients have agreed to them.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Involuntary Admission on Medical Certification: Patient's Right to a Hearing</p> <p>MHL §9.31(a),(b),(f)</p> <p>(a) If....a patient or any relative or friend on behalf of a patient or the Mental Hygiene Legal Services gives notice of a request for a hearing, a hearing shall be held...</p> <p>(b): It shall be the duty of the director upon receiving notice of such request for hearing to forward forthwith a copy of such notice with a record of the patient to the supreme court or the county court....A copy of such notice shall also be given to the Mental Hygiene Legal Service.</p> <p>(f) The papers in any proceeding under this article which are filed with the county clerk shall be sealed and shall be exhibited only to the parties to the proceeding or someone properly interested, upon order of the court.</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p> <p>With regard to MHL §9.31(f), there is no corresponding provision in HIPAA; hence State law provides more protection to PHI in this instance and prevails.</p>
<p>Court Authorization to Retain an Involuntary Patient</p> <p>MHL §9.33(a),(d):</p> <p>(a): If the director determines that a patient admitted upon an application supported by medical certification , for whom there is no court order authorizing retention for a specific period, is in need of retention and if such patient does not agree to remain in the hospital as a voluntary patient, the director shall apply to the supreme court or the county court...for an order authorizing continued retention....The director shall cause written notice of the application to be given to the patient and a copy thereof...to the persons required by this article to be served with notice of such patient's initial application and to the mental hygiene legal service.</p> <p>(d): If the director shall determine that the condition of such patient requires his further</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>retention in a hospital, he shall, if such patient does not agree to remain in such hospital as a voluntary patient, apply during the period of retention authorized by the last order of the court to the supreme court or the county court...for an order authorizing continued retention of such patient...</p>		
<p>Involuntary admission on Certificate of Director of Community Services or his designee</p> <p>MHL §9.37(a),(d):</p> <p>(a): [Effective until 7/01/04]: The director of a hospital, upon application by a director of community services or an examining physician duly designated by him or her, may receive and care for in such hospital as a patient any person who, in the opinion of the director of community services or the director's designee, has a mental illness for which immediate inpatient care and treatment in a hospital is appropriate....</p> <p>(a): [Effective 7/01/04]: The director of a hospital, upon application by a director of community services or an examining physician duly designated by him may receive and care for in such hospital as a patient any person who, in the opinion of the director of community services or the director's designee, has a mental illness for which immediate inpatient care and treatment in a hospital is appropriate and which is likely to result in serious harm to himself or others...</p> <p>(d) After signing the application, the director of community services or the director's designee shall be authorized and empowered to take into custody, detain, transport, and provide temporary care to any such person. Upon the written request of such director or the director's designee, it shall be the duty of peace officers,</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	<p>No preemption: State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p> <p>Under HIPAA, such consent is also not required via the "required to treat," emergency, or "substantial barriers to communicate" exceptions, although an attempt must be made to obtain patient consent. This would have required a change in current practice; however the 8/02 adoption of amendments removing the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes remove this as a concern.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>when acting pursuant to their special duties, or police officers who are members of the state police or of an authorized police department or force or of a sheriff's department to take into custody and transport any such person as requested and directed by such director or his designee. Upon the written request of such director or designee, an ambulance service,....is authorized to transport any such person.</p>		
<p>Emergency admissions for immediate observation, care, and treatment: MHL §9.39</p> <p>(a) The director of any hospital maintaining adequate staff and facilities for the observation, examination, care, and treatment of persons alleged to be mentally ill and approved by the commissioner to receive and retain patients....may receive and retain therein as a patient for a period of 15 days any person alleged to have a mental illness for which immediate observation, care, and treatment in a hospital is appropriate and which is likely to result in serious harm to himself or others... Such person shall be served, at the time of admission, with written notice of his status and rights as a patient under this section. Such notice shall contain the patient's name. At the same time, such notice shall also be given to the mental hygiene legal service and personally or by mail to such person or persons, not to exceed three in number, as may be designated in writing to receive such notice by the person alleged to be mentally ill. If at any time after admission, the patient, any relative, friend, or the mental hygiene legal service gives notice to the director in writing of request for court hearing on the question of need for immediate observation, care and treatment, a hearing shall be held as herein.....It shall be the duty of the director</p>	<p>§164.501:Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI & that is enforceable in a court of law...includes, but is not limited to, court orders/court ordered warrants, subpoenas/ summons issued by a court, grand jury, ..inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; ... and statutes or regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations w/out patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/disclosure complies with/ is limited to the relevant requirements of such law.</p> <p>§164.510(b)(1): A covered entity may disclose to a family member, other relative, close personal friend of the individual or any other person identified by the individual, the PHI directly relevant to such persons involvement with the individual's care or payment related to the individual's care, if the individual is given the opportunity to agree/ prohibit, restrict the disclosure</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p> <p>Note: Under State law, there is no requirement that patient consent be obtained to use/disclose patient information in order to treat the patient. Under HIPAA, such consent is also not required via the "required to treat," emergency, or "substantial barriers to communicate" exceptions, although an attempt must be made to obtain patient consent. This would have required a change in current practice; however, the 8/02 amendments removing the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes remove this as a concern.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>upon receiving notice of such request for hearing to forward forthwith a copy of such notice with a record of the patient to the supreme court or county court...A copy of such notice and record shall also be given to the mental hygiene legal services.</p>	<p>in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order.</p>	
<p>Emergency admissions for immediate observation, care, and treatment in comprehensive psychiatric emergency programs</p> <p>MHL §9.40 [Effective 7/1/04]</p> <p>(a) The director of any comprehensive emergency program may receive and retain patients....may receive and retain therein as a patient for a period not to exceed 72 hours any person alleged to have a mental illness for which immediate observation, care, and treatment in a hospital is appropriate and which is likely to result in serious harm to himself or others...</p> <p>(b) The director shall cause examination of such persons to be initiated by a staff physician of the program as soon as practicable.....</p> <p>(c)At the time of admission to an extended observation bed, such person shall be served with written notice of his status and rights as a patient under this section. Such notice shall contain the patient's name. The notice shall be provided to the same persons and in the manner as if provided pursuant to subdivision (a) of section 9.39 of this article.</p> <p>(e) If at any time....it is determined that such person continues to require immediate observation, care and treatment in accordance with this section...such person shall be removed within a reasonable period of time to an appropriate hospital authorized to receive and retain patients pursuant to section 9.39 of this article and such person shall be evaluated for admission and, if appropriate, shall be admitted to such hospital in accordance with</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.510(b)(1): A covered entity may disclose to a family member, other relative, close personal friend of the individual or any other person identified by the individual, the PHI directly relevant to such persons involvement with the individual's care or payment related to the individual's care, if the individual is given the opportunity to agree, prohibit, or restrict the disclosure</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order.</p>	<p><u>No preemption:</u> State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law.</p> <p>Note: Under State law, there is no requirement that patient consent be obtained to use/disclose patient information in order to treat the patient. Under HIPAA, such consent is also not required via the "required to treat," emergency, or "substantial barriers to communicate" exceptions, although an attempt must be made to obtain patient consent.This would have required a change in current practice; however, the 8/02 amendments removing the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes remove this as a concern.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>section 9.39 of this article..... (f) Nothing in this section shall preclude the involuntary admission of a person to an appropriate hospital pursuant to the provisions of this article.....efforts shall be made to assure that any arrangements for such involuntary admission shall be made within a reasonable period of time.</p>		
<p>Emergency admissions for immediate observation, care, and treatment; powers of certain peace officers and police officers</p> <p>MHL §9.41 [Effective until 7/1/04]</p> <p>Any peace officer, when acting pursuant to his or her special duties, or police officer who is a member of the state police.....Such officer may direct the removal of such person....or...temporarily detain any such person in another safe and comfortable place....in which event, such officer shall immediately notify the director of community services or, if there be none, the health officer of the city of county of such action.</p> <p>MHL §9.41 [Effective 7/1/04]</p> <p>Any peace officer, when acting pursuant to his or her special duties, or police officer who is a member of the state police.....Such officer may direct the removal of such person....or...temporarily detain any such person in another safe and comfortable place....in which event, such officer shall immediately notify the director of community services or, if there be none, the health officer of the city of county of such action.</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p>	<p><u>No preemption</u>: Peace/police officers are not covered entities under HIPAA; hence it does not apply. State law applies.</p>
<p>Emergency admissions for immediate observation, care, and treatment; powers of directors of community services</p> <p>MHL §9.45 [Effective until 7/1/04]</p>	<p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary</p>	<p><u>No preemption</u>: State law applies; the use/disclosure of PHI by the director of community services is required by law and is otherwise authorized pursuant to the DCS' health oversight authority.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>The director of community services or the director's designee shall have the power to direct the removal of any person, within his jurisdiction, to a hospital.....if the parent, adult, sibling, spouse, or child of the person, a committee of the person, a licensed psychologist.....currently responsible for providing treatment services...reports to him that such person has a mental illness for which immediate care and treatment in a hospital is appropriate and which is likely to result in serious harm to him/herself or others. It shall be the duty of peace officers....or police officers....to take into custody and transport any such person. Upon the request of a director of community services...an ambulance service...is authorized to transport any such person. Such person may then be retained in a hospital pursuant...to section 9.39 or 9.40 of this article.</p> <p>MHL §9.45 [Effective 7/1/04] The director of community services or the director's designee shall have the power to direct the removal of any person, within his jurisdiction, to a hospital.....if the parent, adult, sibling, spouse, or child of the person, a committee of the person, a licensed psychologist.....currently responsible for providing treatment services...reports to him that such person has a mental illness for which immediate care and treatment in a hospital is appropriate and which is likely to result in serious harm to him/herself or others..... It shall be the duty of peace officers....or police officers....to take into custody and transport any such person. Upon the request of a director of community services...an ambulance service...is authorized to transport any such person. Such person may then be retained in a hospital pursuant...to section 9.39 of this article.</p>	<p>to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p> <p>§164.512(j): A covered entity may, consistent with applicable law and standards of ethical conduct, use/disclose PHI if it believes, in good faith, that the use/disclosure (i)(A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) is to a person(s) reasonably able to prevent/lessen the threat.</p>	<p>Disclosures/use made by peace and police officers are not governed by HIPAA, since these are not covered entities. Finally, disclosures by health professionals pursuant to this section of law are authorized to lessen or prevent a serious threat to the health/safety of the person with mental illness, due to the "likelihood of serious harm to him/herself or others" criterion within the State statute. Hence, State law applies.</p>
<p>Duties of local officers in regard to their mentally ill</p>	<p>§164.501: Health oversight agency means an agency or authority of the United</p>	

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>MHL §9.47 [Effective until 6/30/05]: (a) All directors of community services, health officers, and social services officials, as defined by the social services law, are charged with the duty of seeing that all mentally ill persons within their respective communities who are in need of care and treatment at a hospital are admitted to a hospital pursuant to the provisions of this article. Social services officials and health officers shall notify the director of community services of any such person coming to their attention. Pending the determination of the condition of an alleged mentally ill person, it shall be the duty of the director of community services and, if there be no such director, of the local health officer to provide for the proper care of such person in a suitable facility.</p> <p>(b) [Effective until 6/30/05]: All directors of community services shall be responsible for the filing of petitions for assisted outpatient treatment (AOT)and for coordinating the delivery of court ordered services with with program coordinators....In discharge of the duties imposed by...section 9.60 of this article, directors of community services may provide services directly, or may coordinate services with the offices of the department or may contract with any public or private provider to provide services for such programs as may be necessary to carry out the duties imposed pursuant to this subdivision.</p>	<p>States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	<p><u>No preemption:</u> Disclosures to the director of community services are permitted by HIPAA without patient consent due to the establishment in this statute of the directors of community services, health officers, and social services officials, as health oversight agencies. Furthermore, some of the express oversight activities authorized by law are set forth in this statute, including the filing of AOT petitions and coordination of the delivery of court ordered care by the director of community services. Uses/disclosures for treatment purposes are permitted since the treatment is required by law, and also because recent amendments to the HIPAA regulations permit uses/disclosures of PHI for treatment purposes without patient consent.</p> <p>Note 1: Under State law, there is no requirement that patient consent be obtained to use/disclose patient information in order to treat the patient. Originally, the HIPAA final rules provided that such consent would not be required via the "required to treat," exception, although an attempt must be made to obtain patient consent, which would have required a change in current practice. The 8/02 amendments removing the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes remove this as a concern.</p> <p>Note 2: To the extent that Directors of Community Services coordinate their health oversight services with other Department offices or contract with</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
		public or private providers to provide AOT services to assist in the performance of their statutory duties, Business Associate Agreements may need to be executed.
<p>Duties of directors of assisted outpatient treatment (AOT) programs</p> <p>MHL §9.48 [Effective until 6/30/05]: (a)(1) Directors of AOT programs ...shall provide a written report to the program coordinators, appointed by the commissioner of mental health pursuant to ...section 7.17 of this chapter.....The report shall...include, but not be limited to...(i) a copy of the court order; (ii) a copy of the written treatment plan; (iii) the identity of the case manager or assertive community treatment team...(iv) the identity of the provider of services; and (v) the date on which services commence(d). (2) The Directors of AOT programs shall ensure the timely delivery of services ...pursuant to court order.</p> <p>(b) Directors of AOT programs shall submit quarterly reports to the program directors regarding the AOT program...the report shall include...(i) the names of individuals served by the program; (ii) the percentage of petitions for AOT granted by the court; (iii) any change in status of assisted outpatient...(iv) a description of material changes in the treatment plans...(v) any change in case managers; (vi) a description of categories of services ordered by the court; (vii) living arrangements of individuals served by the program...(viii) any other information as required by the Commissioner of OMH; and (ix) any recommendations to improve the program.</p>	<p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: <i>Required by law:</i> a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law...it includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation ...; and statutes or regulations that require the production of information, including statutes/regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p>	<p><u>No preemption:</u> State law applies, as all disclosures without patient consent/authorization are permitted by HIPAA. As a designee of the Commissioner of the Office of Mental Health, reports to directors of AOT programs are permitted consistent with its health oversight function. Other disclosures, to the extent incorporated within the AOT court order, are required by law and are therefore permitted under HIPAA without patient consent/authorization.</p> <p>All reports required by the Commissioner of OMH are authorized consistent with its health oversight responsibilities. Hence, State law applies.</p>
Residential treatment facilities for children	§164.501: <i>Health oversight agency</i> means an agency or authority of the United	<u>No preemption:</u> State law applies, as all

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>& youth MHL §9.51 (also see 14 NYCRR Part 583) (a) The director of a residential treatment facility for children & youth may receive as a patient a person in need of care and treatment in such a facility who has been certified as needing such care by the pre-admission certification committee serving the facility.... (b) Persons admitted as inpatients to hospitals operated by the OMH upon the application of the director for the Division for Youth pursuant to section 509 of the Executive law or section 353.4 of the Family Court Actmay, if appropriate..be transferred to a residential facility fo children & youth. The director of the division for youth shall be notified of any such transfer.... (c) The commissioner of OMH shall designate pre-admission certification committees...to evaluate each person proposed for admission or transfer to a residential treatment facility for children & youth. ..Each pre-admission certification committee shall designate five persons...who shall serve as an advisory board to the committee. Such board shall have the right to visit residential treatment facilities for children & youth served by the committee and shall have the right to review clinical records obtained by the pre-admission certification committee and shall be bound by the confidentiality requirements of section 33.13 of this chapter. (d) All applications for admission or transfer.....shall be referred to a pre-admission certification committee for evaluation of the needs of the individual.. (g) Notwithstanding any other provision of law, pre-admission certification committees shall be entitled to review clinical records maintained by any person or entity which pertain to an individual on whose behalf an application is made for admission to a residential treatment facility for children & youth. Any clinical records received by a pre-admission</p>	<p>States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law...it includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation ...; and statutes or regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p>	<p>disclosures without patient consent/authorization are permitted by HIPAA. The Pre-Admission certification are designated under law to implement the health oversight responsibilities of the Commissioner of the Office of Mental Health. Therefore, reports made to them are permitted consistent with their health oversight function. Other disclosures under this statute are required by law and are therefore permitted under HIPAA without patient consent/authorization.</p> <p>The provisions of State law which give additional confidentiality protections to medical portions of a clinical record are more stringent than HIPAA, and hence, State law prevails. Provisions of State law requiring production of information pursuant to the Family Court Act and/or Social Services Law are permitted under the "required by law" exceptions of HIPAA.</p> <p>Note : Business Associate Agreements between OMH and the the pre-admission certification committees may be required, as they are providing a health oversight service on behalf of OMH and PHI is necessary in order to provide this service.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>certification committee and all assessments submitted to the committee shall be kept confidential in accordance with the provisions of section 33.13 of the mental hygiene law, provided, however, that the commissioner may have access to and receive copies of such records for the purpose of evaluating the operation and effectiveness of the committee. Confidentiality of clinical records of treatment of a person in a residential treatment facility required in section 33.13 of this chapter. That portion of the clinical record maintained by a residential treatment facility for children & youth operated by an authorized agency specifically related to medical care and treatment shall not be considered part of the record required to be maintained by such authorized agency pursuant to section 372 of the social services law and shall not be discoverable in a proceeding under section 358-a of the social services law except upon order of the family court; provided, however that all other information required by a social services district or the state department of social services for purposes of sections 358-a, 392, 409-e and 409-f of the social services law shall be furnished on request, and the confidentiality of such information shall be safeguarded as provided in section 460-e of the social services law. for children & youth shall be maintained as</p>		
<p>Emergency admissions for immediate observation, care, and treatment; powers of emergency room physicians</p> <p>MHL §9.57 [Effective until 7/1/04] A physician who has examined a person in an emergency room or provided emergency medical services at a general hospital shall</p>	<p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry</p>	<p>No preemption: State law applies; the use/disclosure by health professionals pursuant to this section of law are authorized to lessen or prevent a serious threat to the health/safety of the person with mental illness, due to the "likelihood of serious harm to him/herself or others" criterion within</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>be authorized to request that the director of the hospital, or his designee, direct the removal of any person, within his jurisdiction, to a hospital if the physician determines upon examination of such person that such person appears to have a mental illness for which immediate care and treatment in a hospital is appropriate and which is likely result in serious harm to himself or others, as defined in section 9.39 of this article..... Upon the request of the physician, the director of the hospital or his designee is authorized to direct peace officers,or police officers....to take into custody and transport any such person. Upon the request of an emergency room physician or the director of the hospital.....an ambulance service...is authorized to transport any such person. Such person may then be retained in a hospital pursuant...to section 9.39 or 9.40 of this article.</p> <p>MHL §9.57 [Effective 7/1/04] A physician who has examined a person in an emergency room or provided emergency medical services at a general hospital shall be authorized to request that the director of the hospital, or his designee, direct the removal of any person, within his jurisdiction, to a hospital if the physician determines upon examination of such person that such person appears to have a mental illness for which immediate care and treatment in a hospital is appropriate and which is likely result in serious harm to himself or others, as defined in section 9.39 of this article..... Upon the request of the physician, the director of the hospital or his designee is authorized to direct peace officers,or police officers....to take into custody and transport any such person. Upon the request of an emergency room physician or the director of the hospital.....an ambulance service...is authorized to transport any such person. Such person may then be retained in a hospital pursuant...to section 9.39 of this article.</p>	<p>out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(j): A covered entity may, consistent with applicable law and standards of ethical conduct, use/disclose PHI if it believes, in good faith, that the use/disclosure (i)(A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) is to a person(s) reasonably able to prevent/lessen the threat.</p>	<p>the State statute. Hence, State law applies.</p> <p>In some cases, communication with the individual may be substantially impaired, or there may be emergency medical circumstances, which, under the original HIPAA final rules, would permit use/disclosure of PHI for treatment purposes without patient consent/authorization, if an attempt to obtain such consent was made. This would have required a change in current practice. The 8/02 amendments, however, remove the requirement to obtain patient consent to use/disclose PHI for treatment, payment, or health care operations purposes, so this is no longer a concern, and the use/disclosure is permitted without patient consent for treatment purposes.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Transport for evaluation; powers of approved mobile crisis outreach teams MHL §9.58 (a) A physician or qualified mental health professional who is a member of an approved mobile crisis outreach team shall have the power to remove, or pursuant to subdivision (b) of this section, to direct the removal of any person to a hospital.....pursuant to subdivision (a) of section 9.39 or section 31.27 of this chapter for purpose of evaluation for admission if such person appears to be mentally ill and is conducting him/herself in a manner which is likely to result in serious harm to the person or others. (b) If the team physician or qualified mental health professional determines that it is necessary to effectuate transport, he or shall shall direct peace officers,or police officers....to take into custody and transport any such person. Upon the request of such physician or qualified mental health professional.....an ambulance service...is authorized to transport any such person. Such person may then be evaluated for admission in accordance with the provisions of section 9.27, 9.39, 9.40, or other sections of this article....</p>	<p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.512(j): A covered entity may, consistent with applicable law and standards of ethical conduct, use/disclose PHI if it believes, in good faith, that the use/disclosure (i)(A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) is to a person(s) reasonably able to prevent/lessen the threat.</p>	<p><u>No preemption</u>: State law applies; the use/disclosure by health professionals pursuant to this section of law are authorized to lessen or prevent a serious threat to the health/safety of the person with mental illness, due to the "likely to result in serious harm to the person or others" criterion within the State statute. Hence, State law applies</p>
<p>"Kendra's Law" - Assisted Outpatient Treatment MHL §9.60 (a)(1): "assisted outpatient treatment" (AOT) means categories of outpatient services which have been ordered by the court pursuant to this section. Such treatment shall include case management services or assertive community treatment team services to provide care coordination, and may also include any of the following categories of services: medication, periodic blood tests or urinalysis to determine compliance with prescribed medications; individual/ group therapy; day/partial day</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the</p>	<p><u>No preemption</u>: State law applies to all of the uses/disclosures of PHI provided for in this statute:</p> <p>1. Because the uses/disclosures required to develop a petition for AOT are necessary in order to become the foundation for a court order (or dismissal of the petition),such uses/disclosures without patient consent or authorization are permitted by HIPAA under the "required by law" and "in the course of a judicial proceeding" exceptions to</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>programming activities; educational/ vocational training/ activities; chemical dependence treatment/counseling and periodic tests for the presence of alcohol/ illegal drugs for persons with a history of chemical dependence; supervision of living arrangements; and any other services within a local/unified services plan developed pursuant to article 41...., prescribed to treat the person's mental illness and to assist the person in living and functioning in the community, or to attempt to prevent a relapse or deterioration that may reasonably be predicted to result in suicide or the need for hospitalization.</p> <p>(c) Criteria for AOT. A patient may be ordered to obtain AOT if a court finds that: (1) the patient is 18 years of age or older; (2) the patient is suffering from a mental illness; and (3) the patient is unlikely to survive safely in the community without supervision, based on a clinical determination; and (4) the patient has a history of lack of compliance with treatment for mental illness that has: (i) at least twice within the last 36 months been a significant factor in necessitating hospitalization in a hospital, or receipt of services in a forensic or other mental health unit of a correctional facility....not including any period during which the person was hospitalized or incarcerated immediately preceding the filing of the petition; (5) the patient is, as a result of his/her mental illness, unlikely to voluntarily participate in the recommended treatment pursuant to the treatment plan; and (6) in view of the patient's treatment history and current behavior, he/she is in need of AOT in order to prevent a relapse or deterioration which would be likely to result in serious harm to the patient or others...and (7) it is likely that the patient will benefit from AOT; and (8) if the patient has executed a health care proxy, the terms of the proxy will be taken into consideration by the court in determining the written treatment plan.</p>	<p>covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order.</p> <p>§164.512(j):A covered entity may use/disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the information cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment.</p>	<p>consent/authorization.</p> <p>2. Uses/disclosures by physicians in the course of providing required testimony are authorized by "in the course of a judicial proceeding" exception to consent/authorization. The requirements set forth to notify and involve the subject of the petition in the hearing are consistent with the requirements set forth in §164.512(e)(1)(ii) which mandate satisfactory assurances of the individual's notification of the request for the use/disclosure of his/her PHI in the course of the judicial proceeding.</p> <p>3. Under the original final HIPAA rule, uses/disclosures back to the court or between and among providers of court ordered services are permitted without patient consent/authorization under the "treatment required by law," and "use/disclosure of PHI required by law" exceptions to HIPAA; furthermore, the recent amendments to HIPAA eliminate the need to attempt to obtain consent, since patient consent is not be required to use/disclose PHI for treatment purposes.</p> <p>4. Because of the essential criteria required to initiate and sustain an AOT petition, uses/disclosures by health professionals pursuant to this section of law are authorized to lessen or prevent a serious threat to the health/safety of the person with mental illness, due to the "likely to result in serious harm to the person or others" criterion within the State statute. Hence, State law applies</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>(e) Petition to the court. (1) A petition for an order authorizing AOT may be filed in the supreme court or county court.....A petition... may only be authorized by the following persons: (i) any person over age 18 with whom the subject of the petition resides; (ii) the parent, spouse, sibling or child of the patient 18 years of age or older; (iii) the director of a hospital in which the subject is hospitalized; (iv) the director of any public or charitable organization, agency, or home providing mental health services to the subject...; (v) a qualified psychiatrist who is either treating the subject; (vi) the director of community services/designee...; (vii) a parole/probation officer assigned to supervise the subject. (2) The petition shall state: (i) each of the criteria for AOT; (ii) facts which support the belief that the criteria have been met; (iii) the subject is reasonably believed to be present in the county where the petition is filed. (3) The petition shall be accompanied by an affidavit/affirmation of a physician that states either the patient has been examined by him/her and AOT is recommended; or the subject refuses to submit to the examination.</p> <p>(f) Service. The petitioner shall cause written notice of the petition to the subject and also to the mental hygiene legal service, health agent (if known), the appropriate program coordinator and the director of community services...</p> <p>(h)Hearing.(1)....the court shall hear testimony and, if advisable, examine the subject in or out of court. (2) The court shall not order AOT unless an examining physician testifies in person at the hearing...(4) a physician who testifies....shall state the facts which support the allegation that the person requires AOT. ...</p> <p>(i). Written treatment plan. (1) The court shall not order AOT unless an examining physician provides to the court a written treatment plan...In developing such plan, the physician shall provide the subject, the treating physician, and an individual designated by the</p>		

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>patient, at the patient's request, to participate in developing the plan. (2) The court shall not order AOT unless a physician testifies to explain the written treatment plan.</p> <p>(j) Disposition. (1) ...if the court finds by clear and convincing evidence the subject meets the criteria for AOT.....the court is authorized to order the subject to receive AOT.....the order shall state the categories of AOT and may also order treatment included in the written treatment plan.....(5) If the petitioner is the director of a hospital, the court order shall direct the hospital to provide/arrange for all categories of AOT. For all other persons, the order shall require the director of community services.....to provide/arrange for all categories of AOT.</p> <p>(n) Failure to comply with AOT. Where in the clinical judgment of a physician, the patient has failed to comply with the court ordered AOT.....and in the physician's clinical judgment the person may be in need of involuntary commitment.....such physician may requestto direct the removal of such person to an appropriate hospital to determine if such person is in need of involuntary commitment.....if such person refuses to take medications as required by the court order.... or fails to take court ordered tests....such physician may take such information into consideration when determining if the involuntary commitment examination is necessary. Peace/police officers may be directed to take into custody/transport such person to a hospital for such examination.</p>		
MHL SECTION 29.29 INCIDENT REPORTING PROCEDURES		
<p>MHL §29.29 The commissioners of OMH and OMRDD shall establish policies and uniform procedures for their offices for the compilation and analysis of incident reports.</p>	<p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary</p>	<p>No Preemption: OMH Policy QA-510 and 14 NYCRR Part 524 are consistent with HIPAA, due in part to the adoption of proposed amendments to HIPAA:</p> <ol style="list-style-type: none"> 1. The Facility and Central Office are

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>OMH Official Policy Directive QA-510 D)4)c)iii) External Reporting: (1) The Executive Director or the administrator on duty is responsible for the timely notification of appropriate persons or organizations of certain incidents in accordance with the provisions of this Policy Directive. (2) Each facility shall have procedures to assure that appropriate notifications occur. Such procedures must generally identify who, within the facility, bears responsibility for making each type of required notification. Copies of all external reports must be concurrently sent to the Bureau of Quality Management in Central Office. The following notifications are required: (A) <u>Commission on Quality of Care for the Mentally Disabled</u> (CQC). 1. The CQC and its Mental Hygiene Medical Review Board must be notified of all patient deaths within 3 working days, using form CQC-100.2. The CQC must be notified in writing of all allegations of patient or child abuse or neglect within 72 hours. B) <u>Food and Drug Administration</u> (FDA). 1. An Adverse Drug Reaction should be reported to the Food and Drug Administration (FDA), following FDA specifications and in accordance with FDA requirements, when the patient outcome is death, life-threatening; hospitalization; disability; congenital anomaly; required intervention to prevent permanent impairment; or reaction. related to the use of a newly marketed drug as part of post-marketing surveillance. 2. Incidents resulting in serious injury or death through the use of medical devices shall be reported to the FDA in accordance with the Safe Medical Devices Act. C) <u>Persons Who May Be Endangered</u>. Any person or persons who are known to be potentially endangered by a patient placed on</p>	<p>to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d) A covered entity may disclose PHI to a health oversight agency for oversight activities authorized by law.</p> <p>§164.512(g) PHI about decedents can be released to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. PHI may also be released to funeral directors to carry out their duties with respect to a decedent. §164.512(b): A covered entity may disclose PHI for the public health activities and purposes described in this paragraph to: (ii) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect..., (iii) a person subject to the jurisdiction of the FDA (A) to report adverse events....</p> <p>§164.512(j): A covered entity may use/disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a</p>	<p>legally divisions within the same covered entity. As a result of new amendments to the privacy regulations (8/02), HIPAA permits the use of PHI by a covered entity without patient consent for health care operations purposes (e.g., quality assurance activities). As OMH Policy QA-510 and 14 NYCRR Part 524 permit use of PHI for incident management purposes w/out patient consent; and HIPAA no longer requires such consent, there is no preemption: State policy/ regulations and HIPAA are consistent.</p> <p>2. Disclosures by OMH to CQC are permitted under the health oversight agency and required by law exceptions.</p> <p>3. Disclosures by OMH to MHLS are permitted under the required by law exception to HIPAA.</p> <p>4. Disclosures by OMH to the FDA are permitted under the required by law exception to HIPAA and the disclosures for public health activities exception.</p> <p>5. Disclosures by OMH to medical examiners/coroners, provided they are disclosures necessary for such entities to perform their statutory duties, are consistent with HIPAA and are permitted.</p> <p>6. Disclosures by OMH to law enforcement authorities and endangered persons in the case of patients placed on missing/escape status are permitted under the express exception to HIPAA to lessen a serious and imminent threat to the health and safety of a person.</p> <p>7. The provisions of OMH policy requiring the reporting of crimes on program premises is consistent with the exception to use/disclosures under</p>

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<p>missing patient-escape status must be notified immediately.</p> <p>(D) <u>Local Law Enforcement Authorities</u></p> <p>1. Local law enforcement authorities must be notified in a timely manner of any incident when it appears that a crime may have occurred.</p> <p>2. Local law enforcement authorities shall also be notified as soon as possible when a patient has been placed on missing patient-escape status.</p> <p>(E) <u>Medical Examiner/Coroner</u>. When a patient dies while an inpatient of a State-operated facility, the County Medical Examiner or Coroner must be notified immediately in accordance with applicable OMH Policy.</p> <p>(F) <u>Board of Visitors and the Mental Hygiene Legal Service (MHLS)</u>. The Board of Visitors and the Mental Hygiene Legal Service must both be notified within 3 working days of any incident of alleged child or patient abuse or neglect. The Board of Visitors and MHLS must also both be notified of the results of the investigation of such allegations.</p> <p>(G) <u>New York Statewide Central Register of Child Abuse and treatment (SCR)</u>.</p> <p>1. The New York Statewide Central Register of Child Abuse and Maltreatment (SCR) must be notified immediately, by telephone, of any incident of alleged child abuse or neglect. The Social Services Law mandates the reporting to the SCR of allegations of abuse or neglect as defined in C)3) of this policy directive, as well (abuse/ neglect of children, including suspected se or neglect of a child by a parent. 2. If a family member/ visitor harms a child/ adolescent on the property of a State-operated facility or program, such an event would be identified as an incident using applicable incident terminology and would also be</p>	<p>person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the information cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment.</p> <p>§164.512(f)(5): Crime on program premises. A covered entity may disclose to a law enforcement official PHI that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity. §164.510(b)(1): A covered entity may disclose to a family member, other relative, close personal friend of the individual or any other person identified by the individual, the PHI directly relevant to such persons involvement with the individual's care or payment related to the individual's care, if the individual is given the opportunity to agree, prohibit, or restrict the disclosure.</p> <p>§164.501 Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.</p> <p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>OCR HIPAA Implementation Guidance: (7/01) "Q: Will the consent requirement restrict the ability of providers to consult with other providers about a patient's condition?A: No. A provider with a direct treatment relationship with a patient would have to have initially obtained consent to use that patient's health information for treatment purposes. Consulting with another health care provider about the patient's case falls within the definition of "treatment" and, therefore, is permissible. If the provider being consulted does not otherwise have a direct treatment relationship with the patient, that provider does not need to obtain the patient's consent to engage in the consultation. But Note: Recent amendments eliminate this requirement:</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(f)(2): ...A covered entity may disclose PHI in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that: (i) the covered entity may disclose only the following information: (A) Name/address; (B) Date/place of birth; (C) SS#; (D) ABO blood type and rh factor; (E) type of</p>	<p>HIPAA for reporting same.</p> <p>8 Disclosures by OMH to the Board of Visitors are permitted under the required by law and health oversight exceptions to HIPAA.</p> <p>9. Disclosures to the NYS Central Register of Child Abuse are permitted under the HIPAA exception permitting such reports for public health purposes and as authorized by law.</p> <p>10. Disclosures to next of kin are authorized, provided the patient has previously been given the opportunity to agree or object to such notifications; OMH policy is generally consistent with this requirement.</p> <p>11. Disclosures to contact persons are permitted if authorized by the patient.</p> <p>12. Disclosures to other treatment providers, with a direct treatment relationship with the patient, are permitted without patient consent as a result of the adoption of the 8/02 amendments to HIPAA allowing use/disclosure of PHI for treatment purposes without patient consent.</p> <p>13. Disclosures to the Department of Labor, Department of Education, Department of Health, and National Practitioner Data Bank are probably permitted under the required by law and/or health oversight agency exceptions to HIPAA; Counsel's Office will need to advise in individual circumstances. Also note that in some cases, it might be possible to utilize de-identified information to some extent.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>reported to the SCR as abuse.</p> <p>(H) <u>Next of Kin</u>. Unless the patient involved in an incident is an adult who objects to such notification, the patient's next of kin or guardians shall be notified immediately of allegations of abuse or neglect, incidents involving missing patients or incidents involving patient death or injury. In such cases, next of kin or guardians shall also be notified of the outcomes of the investigation and review process for the most serious incidents.</p> <p>(I) <u>Contact Persons and Other Mental Health Programs</u>. When an inpatient of a State-operated psychiatric facility is considered missing, any contact person identified in the missing person's case record ... shall be notified. In addition, any mental health program, including a case management program, which recently provided services to the person or is likely to encounter the missing person, shall be notified.</p> <p>(J) <u>New York State Education Department, New York State Health Department, and National Practitioner Data Bank</u>. In cases where possible misconduct of licensed practitioners or physicians is related to an incident, Counsel's Office must be contacted for advice regarding notification of the NYS Education Department, NYS Department of Health, and the National Practitioner Data Bank, as applicable.</p> <p>(K) <u>New York State Department of Labor</u>. In cases where an incident results in the fatality or inpatient hospitalization of an employee of OMH, Counsel's Office and the Bureau of Human Resources must be contacted for advice regarding notification of the New York State Department of Labor, Division of Safety and Health.</p> <p>Note: These requirements are also included in 14 NYCRR Section 524.7, and are</p>	<p>injury; (F) date/time of treatment; (G) date/time of death, if applicable; and (H) description of distinguishing physical characteristics...</p> <p>§164.512(f)(3): ...a covered entity may disclose PHI in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime,if (ii) the individual agrees to the disclosure, or (ii) the covered entity is unable to obtain the individual's agreement because of incapacity or other emergency, provided that (A) the law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the individual; (B) the law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and (C) the disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of its professional judgment.</p>	

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p><i>referenced, as applicable, in OMH Official Policy Manual ## QA-515, QA-520, QA-530, and PC-450.</i></p>		
MHL SECTION 31.06 CHILD ABUSE PREVENTION		
<p>MHL §31.06: All facilities described in subdivision (a) of section 31.02 of this article shall, pursuant to regulations of the Commissioner of OMH: (i) develop, maintain and disseminate written policies and procedures pursuant to title 6 of article 6 of the Social Services Law and applicable provisions of Article 10 of the Family Court Act, regarding the mandatory reporting of child abuse or neglect, reporting procedures and obligations of persons required to report, provisions for taking a child into protective custody, mandatory reporting of all deaths, immunity from liability, penalties for failure to report, and obligations for the provision of services and procedures necessary to safeguard the life or health of the child; and (ii) establish, and implement on an ongoing basis, a training program for all current and new employees regarding the policies and procedures established pursuant to this section.</p> <p><i>Also see: OMH Official Policy Manual QA-515</i></p>	<p>§164.512(b): A covered entity may disclose PHI for the public health activities and purposes described in this paragraph to: (ii) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect.</p>	<p><u>No preemption:</u> HIPAA specifically authorizes the reporting of child abuse as required in State law; State and Federal laws are consistent; therefore State law applies.</p>
MHL SECTION 33.13: CLINICAL RECORDS; CONFIDENTIALITY		
Definitions	§164.501: <i>Individual</i> means the person who is the subject of protected health	<u>No preemption:</u> State law applies and is

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>MHL §33.13(a): <i>Patient or client</i> (defined MHL §33.16(5)): means an individual concerning whom a clinical record is maintained or possessed by a facility as defined in §33.16(3).</p> <p>14 NYCRR §505.4(k): <i>Protected individuals</i> means a person who is the subject of an HIV-related test or who has been diagnosed as having HIV infection, AIDS or HIV-related illness.</p>	<p>information.</p>	<p>not preempted because the Federal law is not contrary to State law; the two laws are similar.</p> <p>With regard to the regulatory term “protected individuals,” again, State law applies and is not preempted because the Federal law is not contrary to State law; the term “individual” in Federal law includes the term “protected individual” as HIV related information is within the definition of PHI.</p>
<p>Definitions</p> <p>MHL §33.13(a): <i>Clinical record</i> contains information on all matters relating to the admission, legal status, care, and treatment of the patient or client and shall include all pertinent documents relating to the patient or client.</p>	<p>§160.103: <i>Health Information</i> means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p>	<p><u>No preemption</u>; State law applies and is not preempted because the Federal law is not contrary to State law; the two laws are generally similar, since breadth of State law would encompass the types of information included in the HIPAA definition of “health information.”</p>
<p>Incident Reports:</p> <p>OMH Guidebook(Appendix J): Clinical records do not include incident reports.</p> <p>Education Law §6527: Neither the proceedings nor the records relating to performance of a medical or dental malpractice prevention program nor any report required by DOH pursuant to section 2805-I of the PHL, including the investigation of an incident pursuant to section 29.29 of the MHL shall be subject to disclosure under Article 31 of the CPLR except as provided by any other provision of law.</p> <p>Case Law: (1) Reports contained in psychiatric hospital's investigation file...including two</p>	<p>§160.103: <i>Health Information</i> means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p>	<p><u>No preemption</u>; State law applies and is not preempted because the Federal law is not contrary to State law. State case law provides that incident reports do not relate to the health care of a patient, but rather to the methodology and manner in which services were rendered; hence, they are properly excluded from the Federal law definition of “health information,” which does not expressly include this type of information.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>incident reports by designated staff persons, and incident or investigation report prepared by state agency, related to investigation of allegations....which were required to be reported to the Department of Health, and thus were incident reports exempt from disclosure in action brought by patient against hospital. <u>Katherine F. ex rel. Perez v. State</u>, 94 N.Y.2d 200, 700 N.Y.S.2d 231, 723 N.E.2d 1016 (1999).</p> <p>(2) Incident reports made by employees at state mental health facility in connection with treatment of severely retarded patient and of other residents at facility, were part of procedure intended to reduce patient and employee injuries, and thus were obtained or maintained pursuant to review procedure and were privileged from discovery under Education Law in action brought by administrator of estate of patient for injuries sustained by patient while at facility. <u>Finnegan v. State</u>, 179 Misc. 2d 694, 686 N.Y.S. 2d 589 (1999)</p> <p>(3) Investigation report prepared on behalf of OMH by consultant did not relate to patient's care and treatment, a requirement in order to consider it part of the clinical record, but rather found that it revealed the methodology and manner in which the patient received treatment. This characterized it as a quality assurance document, rather than part of the clinical record releaseable to patient under the Freedom of Information Act. <u>Zabielski v. Stone</u> (2002)</p>		
<p>Educational Records:</p> <p>OMH Guidebook(Appendix J): Clinical records do not include educational records</p> <p>MHL §33.16(f): Applicability of federal law.</p>	<p>§164.501: Protected Health Information ...excludes individually identifiable health information in:(i) Educational records covered by the Family Education Right and Privacy Act, 20 U.S.C. 1232g....</p>	<p><u>No preemption:</u> State and Federal laws are consistent.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Whenever federal law or applicable federal regulations restrict, or as a condition for the receipt of federal aid require, that the release of clinical records or information be more restrictive than is provided under this section, the provisions of federal law or federal regulations shall be controlling.</p> <p>20 U.S.C. §1232g (FERPA): provides parents of students and eligible students with privacy protections and rights for the records of students maintained by federally funded educational agencies or institutions or persons acting for these agencies or institutions.</p>		
<p>Statistical Information</p> <p>MHL §33.13(b): (Effective until June 30, 2005) The Commissioners may require that statistical information about patient or clients be reported to the offices.</p> <p>(Effective June 30, 2005) The Commissioners may require that statistical information about patient or clients be reported to the offices. Names of patients treated at outpatient or nonresidential facilities, at hospitals licensed by OMH and at general hospitals shall not be required as part of any such reports.</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d) A covered entity may disclose PHI to a health oversight agency for oversight activities authorized by law.</p> <p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p>	<p>No preemption: State law applies; the use/disclosure of PHI is required by law; provided it complies with that law, it is not preempted, though the disclosure must be limited to the relevant requirements of the law. Note that even post June 2005, elimination of patient names does not necessarily make the information de-identified, but nonetheless, the use/disclosure is permitted.</p> <p>As health oversight agencies, the Commissioners of OMH and OMRDD can request statistical information that is PHI as part of its regulatory and licensing oversight function.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Court Orders</p> <p>MHL §33.13(c)(1): Clinical records shall be released w/out patient consent pursuant to a court order after a finding that the interests of justice significantly outweigh the need for confidentiality</p> <p>CPLR§4507: “privilege” or exempt certain patient information held by physicians, RNs, LPNs, registered psychologists, and registered social workers, from testimonial disclosure</p>	<p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814: 3)</p>	<p><u>No preemption</u> State law applies, since it is more strict by requiring a court order after specific findings have been made, or prevents testimony.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Mental Hygiene Legal Services (MHLS)</p> <p>MHL §33.13(c)(2): Clinical records shall be released w/out patient consent to Mental Hygiene Legal Services</p> <p>MHL §47.03: MHLS has authority to be granted access to all books, records, and data necessary for it to carry out its functions, provided that where federal regulations restrict a facility re: release of info in the clinical record of a patient or restrict disclosure of identity of patient or access to the patient to a greater extent than allowed under this law, the federal regulations shall be controlling.</p> <p>MHL §9.11: (effective until 7/1/04): Except as to informal patients and patients admitted pursuant to section 9.39 or 9.40, the director of a hospital shall, within 5 days.....after the admission of any patient, forward to MHLS a record of such patient and shall simultaneously forward to the department such information from the record as the commissioner by regulation shall require. Such information from the record in the department shall only be accessible in the manner set forth in section 33.13.</p> <p>MHL §9.11: (effective 7/1/04): Except as to informal patients and patients admitted pursuant to section 9.39, the director of a hospital shall, within 5 days.....after the admission of any patient, forward to MHLS a record of such patient and shall simultaneously forward to the department such information from the record as the commissioner by regulation shall require. Such information from the record in the department shall only be accessible in the</p>	<p>§164.502(a): A covered entity may not use or disclose PHI except as permitted or required by this subpart or subpart C of part 160 of this subchapter.</p> <p>§164.502(g): A "personal representative" can fulfill the role of the individual about whom PHI pertains if the representative has authority to act on behalf of the individual in making decisions about health care.</p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid under this section. (p. 82811:1)</p>	<p><u>Fact Dependent:</u></p> <p>In cases where MHLS is a patient's "personal representative," i.e., MHLS has legal authority to make decisions regarding a patient's health care, information can be disclosed without specific patient consent or authorization. To the degree, however, that MHL §47.03 (f) indicates that federal regulations that place greater restrictions on release of information about patients shall prevail. Therefore, in most cases, patient authorization will be necessary for release of information to MHLS.</p> <p>Other notifications, such as the requirement in MHL §29.29 for facilities to notify the MHLS of all reported allegations of patient abuse or neglect within 3 working days, and disclosures required throughout Article 9 (e.g. MHL §9.09, 9.11, 9.25, 9.31, 9.33), are not preempted and are therefore permitted under the "required by law" exemption to HIPAA since the use or disclosure is required by law. This, however, is not a general rule under MHL §47.03.</p>

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<p>Attorneys MHL §33.13(c)(3) An attorney representing a patient on the matter of his involuntary hospitalization can be provided access to the patient's clinical record.</p>	<p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814: 3)</p>	<p><u>No preemption</u>; should generally operate together, provided satisfactory assurances have been provided by the attorney per the HIPAA regulations. (p. 82815:1)</p>
<p>CQC MHL §33.13(c)(4): Records can be released to CQC or other person/agency under contract with CQC to provide protection and advocacy services as provided for by federal law, irrespective of patient consent.</p> <p>MHL §45.09:(a) The commission, any member or any employee designated by the commission, must be granted access at any and all times to any mental hygiene facility or adult home or residence for adults in which 25 % of more residents have at any time received or are receiving services from a mental hygiene provider which is licensed, operated, or funded by OMH or OMRDD in order to carry out the functions of the commission as provided for in section 45.10 of this article....ad to all books, records and data pertaining to any such facility deemed necessary for carrying out the commission's functions, powers and duties.</p>	<p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions, ...or other activities necessary for the oversight of the health care system... (p. 82814:2)</p>	<p><u>No Preemption</u>: Federal statute (42 USCA §10805) provides for the establishment of a system of protection and advocacy services for psychiatric patients who may be the subject of abuse or neglect. In New York, this function is vested in CQC. Coupled with its New York State statutoru authority, CQC meets the HIPAA definition of a health oversight agency, and as such they are permitted to receive PHI without patient authorization/consent. Hence, the laws are not inconsistent and State law applies.</p>
<p>Medical Review Board/State Commission of Corrections MHL §33.13(c)(5): Records can be released to the Medical Review Board of the State Commission of Corrections, when requested in connection with a patient death, or with patient consent and in exercise of its statutory duties.</p>	<p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid</p>	<p><u>No preemption</u>: State law applies, in that patient "consent" (will need to fulfill requirements of HIPAA authorization) is necessary to disclose information. In cases of decedent information, the HIPAA health oversight exception should apply.</p>

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	<p>under this section. (p. 82811:1)</p> <p>§164.512(g) PHI about decedents can be released to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. PHI may also be released to funeral directors to carry out their duties with respect to a decedent.</p> <p>§164.512(d): PHI can be released to health oversight agencies for oversight activities authorized by law, including administrative investigations.</p>	
<p>Endangered individuals (Tarasoff)</p> <p>MHL §33.13(c)(6): Patient information can be released to an endangered individual <u>and</u> a law enforcement official when a treating psychiatrist or psychologist has determined that a patient presents a “serious & imminent” danger to that individual.</p>	<p>§164.512(j): A covered entity may use/disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the information cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment.</p>	<p><u>No preemption:</u> State and Federal laws are consistent; State law applies.</p>
<p>Consent</p> <p>MHL §33.13(c)(7) Patient information can be released, with consent of the patient or of someone authorized to act on patient's behalf, to persons/entities who have a demonstrable need for such information provided such disclosure will not reasonably be expected to be detrimental to the patient or others.</p>	<p>§164.502(a)(1): A covered entity is permitted to use/disclose PHI to the patient (including a patient's personal representative, i.e., someone authorized to act on patient's behalf to make health care decisions).</p>	<p><u>No preemption:</u> State law prevails, in that it offers greater restrictions on disclosure to patient information, i.e. there must be a demonstrable need to know and no detrimental impact.</p>
<p>State Board for Professional Medical Conduct/Office of Professional Discipline:</p> <p>MHL §33.13(c)(8): Patient information can be disclosed (irrespective of patient consent) to the State Board for Professional Medical Conduct, the Office of Professional Discipline, or their respective representatives when the Board or Office has requested such information in the exercise of its statutory function, powers and duties (provided, however, that no such</p>	<p>§164.512(d) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p> <p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p>	<p><u>No preemption:</u> State and Federal laws are consistent; State law applies.</p>

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information may be released when the patient is also the subject of the Board's inquiry, except pursuant to a court order).		
<p>Payment</p> <p>MHL §33.13(c)(9)(i):With consent of appropriate Commissioner, Patient information may be disclosed w/out patient consent to governmental agencies, insurance companies, and other third parties requiring information necessary for payment. Such information shall be limited to the information required.</p>	<p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information..... <i>revised 8/02</i></p>	<p><u>No Preemption:</u> NY law permits disclosure of PHI for payment purposes without patient consent; the newly adopted amendments to HIPAA also do not require such consent.</p>
<p>Missing persons/criminal investigations:</p> <p>MHL §33.13(c)(9)(ii) With consent of appropriate Commissioner, patient information may be disclosed to persons and agencies needing information to locate missing persons or to governmental agencies in connection with criminal investigations, such information to be limited to identifying data concerning hospitalization.</p>	<p>§164.512(f)(1),(2): A covered entity may use/disclose PHI for law enforcement purposes, including in response to a law enforcement official's request for such info to identify and locate a suspect, fugitive, material witness, or missing person, provided that the info disclosed is limited as prescribed. (P.82815:2,3)</p>	<p><u>Fact Dependent:</u> State and Federal laws are generally consistent, provided requestor of PHI fits the definition of "law enforcement official" in HIPAA.</p>
<p>Qualified researchers:</p> <p>MHL §33.13(c)(9)(iii)With consent of appropriate Commissioner, patient information can be released to "qualified researchers" (certain persons licensed under the Education Law or other persons deemed competent/qualified by IRB or other human research committee constituted by OMH) when approved by the IRB or other committee constituted by OMH under certain circumstances.</p>	<p>§164.512(i): A covered entity may disclose PHI w/out patient consent for research purposes with IRB or privacy board approved waiver.(p.82816:2,3)</p> <p>Note: recent amendments modify this requirement to streamline reviews, but do not remove requirement for IRB approval.</p>	<p><u>Preempted in Part:</u> Language of NYS statute is broadly drafted so that it can be interpreted, to a large part, as consistent with HIPAA. However, IRB review and waiver under HIPAA contains specific requirements that must be satisfied before PHI can be used/disclosed for research w/out patient consent. Otherwise, patient authorization is required. These provisions preempt State law.</p> <p><i>Note: current OMH/RFMH practice is to obtain specific patient "consent" (really an authorization).</i></p>
<p>Coroners, county medical examiners:</p>	<p>§164.512(g): A covered entity may disclose PHI to a coroner or medical examiner</p>	<p><u>No preemption:</u> State and Federal laws</p>

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<p>MHL §33.13(c)(9)(iv) With consent of appropriate Commissioner, patient information may be disclosed w/out patient consent to a coroner, a county medical examiner, or the chief medical examiner for NYC upon the request of a facility director that an investigation be conducted into the death of a patient about whom the facility maintains such information. Disclosure limited to necessary information.</p>	<p>for the purpose of identifying a deceased person, determining cause of death, or other duties as authorized by law. (P. 82816: 1)</p>	<p>are consistent; State law applies.</p>
<p>Endangered patient or public at large:</p> <p>MHL §33.13(c)(9)(v): With consent of appropriate Commissioner, patient information may be released to appropriate persons & entities when necessary to prevent imminent serious harm to the patient or another person</p>	<p>§164.512(j)(1),(2):A covered entity may use or disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the info cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment. (p. 82817:2)</p>	<p><u>No preemption:</u> While the State law applies to disclosures and HIPAA applies to both uses and disclosures; a distinction between “use” and “disclosure” has never been made in State law; such term is undefined. Therefore, it is reasonable to assume that in general, State law and HIPAA are consistent in intent. State law, however, is more stringent in that disclosure is permitted “when necessary” to prevent serious and imminent harm, while a “good faith” belief is the standard in HIPAA. Hence, State law applies.</p> <p>Note: It should be noted that HIPAA would limit uses/disclosures to someone <u>other than the target</u> of the threat if the information was learned in the course of treatment to affect the propensity to commit the criminal conduct forming the basis for the disclosure, e.g. sex offender treatment.</p>
<p>District Attorneys</p> <p>MHL §33.13(c)(9)(vi): With consent of appropriate Commissioner, patient information may be released to a district attorney when such request is in connection with and necessary to the furtherance of a criminal</p>	<p>§160.501:Law enforcement official means an officer or employee of any agency or authority, of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) investigate or conduct an official inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.</p>	<p><u>Fact Dependent:</u> State and Federal laws are generally consistent in intent, provided that the requisite conditions listed in the HIPAA exceptions are met. State law is more stringent by relating only to crime victims who are victims of patient or client abuse. For all other</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>investigation of patient/client abuse.</p>	<p>§164.512(f)(1): A covered entity may disclose PHI for a law enforcement purpose to a law enforcement official...(i) in compliance with and as limited by the relevant requirements of:(A) a court order or court-ordered subpoena or summons issued by a judicial officer; (B) a grand jury subpoena; or(C) an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:(1) the information sought is relevant and material to a legitimate law enforcement inquiry;(2)the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and(3)de-identified information could not reasonably be used.</p> <p>§164.512(f)(3):a covered entity may disclose PHI in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures subject to paragraphs (b)and(c) of this section, if: (i) the individual agrees to the disclosure; or (ii)the covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that (A) the law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred; and such information is not intended to be used against the victim; (B) the law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would materially and adversely be affected by waiting until the individual is able to agree to the disclosure; and (C) the disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.</p>	<p>crimes, HIPAA would apply (subject to provisions requiring the person that is the subject of the PHI to agree to the disclosure unless it cannot be obtained, in accordance with the rule). Furthermore, under State law, information re: patient abuse may only be disclosed to a district attorney, while HIPAA allows disclosures for other crimes to a law enforcement official, which is more broadly defined.</p> <p>Note: Other disclosures to district attorneys may be authorized if otherwise required by law.</p>
<p>Correctional Facilities:</p> <p>MHL §33.13(c)(10): Patient information necessary for making a determination regarding a current inmate's health care, security, safety or ability to participate in programs may be disclosed to a correctional facility when the chief administrative officer has requested same. Information released may be limited to a summary of the record.</p> <p>Division of Parole: Patient information can be disclosed to DoP when it has requested same with respect to a person under its jurisdiction or when the inmate is within 2 weeks of release from a state correctional facility.</p>	<p>§164.512(k)(5): A covered entity may disclose PHI about an inmate or individual in lawful custody to a correctional institution or a law enforcement official having lawful custody of such individual about such inmate or individual if the PHI is necessary for(1) the provision of health care to the person; (2) the health and safety of the person or other inmates; (3) the health and safety of officers/employees; (4) the health and safety of those transporting/transferring the person; (5) law enforcement on the premises of the correctional institution; (6) administration and good order of the institution.</p> <p>It is noted that an individual is no longer considered an "inmate" when released on parole, probation, supervised release, or is no longer in lawful custody.(p. 82818:1,2)</p>	<p><u>Preempted in Part:</u> For disclosures to correctional institutions and to DoP for persons about to be released from a correctional facility, the laws are consistent, and there is no preemption. State law applies.</p> <p>However, for disclosures to DoP with regard to persons who have been released to parole, the NYS Statute is preempted and consent or authorization for release of PHI is required.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Qualified persons</p> <p>MHL §33.13(c)(11) MHL §33.16(a)(6)</p> <p>Patient information can be released, irrespective of patient consent, to a patient, guardian appointed pursuant to Section 17-A of the Surrogate's Court Procedure Act, or committee for an incompetent, or parent/guardian of an infant or other legally appointed guardian of an infant, or a parent, spouse or adult child of an adult patient who may be entitled to request access to a record pursuant to Section 33.16 of the MHL.</p>	<p>§164.502(a)(1)(i): A covered entity can release PHI w/out consent to the individual. "Individual" is defined in §164.501 as the person who is the subject of the health information.</p> <p>§164.502(g) Requires covered entities to treat "personal representatives" as the individual for purposes of HIPAA rights (e.g. signing consents, authorizations, access, copying, and correction). Personal representatives include: (1) with respect to adults and emancipated minors, personal representatives who have under applicable law authority to act on behalf of an adult or emancipated minor in making decisions relating to health care; (2) with respect to unemancipated minors, a parent, guardian, or other person acting in loco parentis provided that when a minor lawfully obtains a health care service without the consent of or notification to a parent, guardian or other person acting in loco parentis, the minor shall have the exclusive right to exercise the rights of an individual with respect to the PHI relating to such care; (3) with respect to deceased persons, an executor, administrator, or other person authorized under applicable law to act on behalf of the decedent's estate. (p. 82492:3)</p>	<p><u>No Preemption:</u> State law and HIPAA are generally consistent. State law is not contrary to HIPAA; State law applies.</p>
<p>Director of Community Services:</p> <p>MHL §33.13(c)(12): Patient information can be disclosed to a Director of Community Services when in connection with "the exercise of his statutory functions, powers and duties pursuant to MHL §41.13" which authorizes the provision of local services to the mentally disabled in order to assure appropriateness and continuity of services for those in need of such services.</p>	<p>§164.512(d)(3) PHI may be disclosed to health oversight agencies for oversight activities authorized by law, including licensure or disciplinary actions. (p. 82814:2)</p> <p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.512(k): A covered entity that is a government agency administering a government program providing public benefits may disclose PHI relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of PHI is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.</p>	<p><u>No preemption:</u> To the extent that a use or disclosure is made to a DCS in the exercise of its statutory health oversight duties and/or specialized government functions (i.e., as administrators of the Medicaid program), it is not preempted.</p> <p>Note: for supporting reference regarding a determination that the Director of Community Services constitutes a health oversight agency, see Mental Hygiene Law Article 41 and 14 NYCRR §102.7.</p>
<p>NYS Division of Criminal Justice Services</p> <p>MHL §33.13(c)(13): Patient information can be released to DCJS for the sole purpose of providing, facilitating, evaluating or auditing access by the Commissioner of OMH to</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p> <p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that</p>	<p><u>No preemption:</u> Assuming DCJS is not a covered entity under HIPAA, there are no HIPAA restrictions on its disclosures to OMH. OMH is authorized to receive criminal justice information by State law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>criminal history information pursuant to MHL §7.09.</p> <p>MHL §7.09(j): The Commissioner of OMH is authorized to have access to criminal history information contained in the central data facility established by DCJS; summary reports can be included in patient records for purposes of making decisions regarding care and treatment, health and safety, privileges and discharge planning for patients admitted to/retained in hospitals operated by OMH.</p>	<p>is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(k)(5): A covered entity may disclose PHI about an inmate or individual in lawful custody to a correctional institution or a law enforcement official having lawful custody of such individual about such inmate or individual if the PHI is necessary for (1) the provision of health care to the person; (2) the health and safety of the person or other inmates; (3) the health and safety of officers/employees; (4) the health and safety of those transporting/transferring the person; (5) law enforcement on the premises of the correctional institution; (6) administration and good order of the institution.</p> <p>§164.501: <i>Correctional institution:</i> means any penal or correctional facility, jail, reformatory, detention center, or residential community program ...for the confinement or rehabilitation of persons charged with or convicted of criminal offense or other persons held in lawful custody. Other persons held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.</p>	<p>To the extent the information disclosed by OMH is information regarding an inmate, and the disclosures to DCJS are necessary in order for the administration and good order of the facility (e.g. to evaluate and audit OMH's access to the information, HIPAA would permit OMH to disclose PHI about inmates back to DCJS.</p> <p><i>Note: A government agency to-government agency MOU may need to be executed and/or amended , as applicable, to reflect Business Associate requirements of HIPAA.</i></p>
<p>Other Service Providers:</p> <p>MHL §33.13(d) Patient information can be shared among facilities or others providing services for such patients pursuant to an approved local or unified services plan, or pursuant to agreement with Department of Mental Hygiene. Hospital. Emergency rooms (Article 28) can exchange, electronically or otherwise, information with other Article 28 hospital emergency rooms and/or hospitals</p>	<p>§164.501 <i>Treatment</i> means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party, consultation between health care providers relating to a patient, or the referral of a patient for health care from one health care provider to another.</p> <p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>OCR HIPAA Implementation Guidance: (7/01) "Q: Will the consent requirement</p>	<p>No Preemption: NY law permits disclosure of PHI with other treatment providers for treatment purposes without obtaining patient consent; newly adopted amendments to HIPAA also permit uses/disclosures of PHI for treatment purposes without general consent.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>licensed/operated by OMH. Information disclosed must continue to be treated as confidential and any limitations imposed on the party giving the information shall apply to the party receiving the information.</p>	<p>restrict the ability of providers to consult with other providers about a patient's condition?</p> <p>A: No. A provider with a direct treatment relationship with a patient would have to have initially obtained consent to use that patient's health information for treatment purposes. Consulting with another health care provider about the patient's case falls within the definition of "treatment" and, therefore, is permissible. If the provider being consulted does not otherwise have a direct treatment relationship with the patient, that provider does not need to obtain the patient's consent to engage in the consultation.</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	
<p>Licensed Providers</p> <p>MHL §33.13(e): Clinical information tending to identify patients and clinical records maintained at a facility not operated by OMH shall not be a public record and shall not be released to any person or facility outside of such facility except pursuant to subdivisions (b),(c) or (d) of this section (<i>see analysis for each of these subdivisions, infra</i>) . The director of such a facility may consent to the release of such information and records, subject to regulation by the Commissioner, pursuant to the exceptions stated in subdivision (c) of this section (<i>infra</i>), provided that, for the purpose of this subdivision, such consent shall be deemed to be the consent otherwise required of the Commissioner pursuant to subdivision (c) of this section. Nothing in this subdivision shall be construed to limit, restrict, or otherwise affect access to such clinical information or records by the mental hygiene legal service, the commission on quality of care for the mentally disabled or the offices when such</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p> <p>§164.502(a): A covered entity may not use or disclose PHI except as permitted or required by this subpart or subpart C of part 160 of this subchapter.</p> <p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid under this section. (p. 82811:1)</p>	<p><u>No Preemption:</u> State law extends the confidentiality provisions of MHL §33.13 to licensed providers, in addition to those directly operated by the State. To the extent they are covered entities, they must be in compliance with HIPAA. In these cases, the preemption analysis <i>infra</i> on the various provision of MHL§ 33.13 will likewise apply.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
access is authorized elsewhere in law.		
<p>Minimum Necessary</p> <p>MHL §33.13(f): Any disclosure made pursuant to this section shall be limited to that information necessary in light of the reason for disclosure. Information so disclosed shall be kept confidential by the party receiving such information and the limitations on disclosure in this section shall apply to such party. Except for disclosures made to the mental hygiene legal service, to persons reviewing information or records in the ordinary course of insuring that a facility is in compliance with applicable quality of care standards, or to governmental agencies requiring information necessary for payments to be made to or on behalf of patients pursuant to contract or in accordance with law, a notation of all such disclosures shall be placed in the clinical record of that individual who shall be informed of all such disclosures upon request; provided, however, that for disclosures made to insurance companies licensed pursuant to the insurance law, such a notation need only be entered at the time the disclosure is first made.</p>	<p>§164.502(b) Minimum Necessary: (1)When using or disclosing PHI or when requesting PHI from another covered entity, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the purpose of the use, disclosure, or request. (2) This does not apply to: (i) Disclosures to/ requests by a health care provider for treatment; (ii) Uses or disclosures made to the individual, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization; (iii) Disclosures made to the Secretary of HHS; (iv) Uses or disclosures that are required by law, and (v) Uses or disclosures that are required for compliance with applicable requirements of this Subchapter. (p. 82805,82806)</p> <p>§164.528: Accounting of disclosures of PHI (a)(1): An individual has a right to receive an accounting of disclosures of PHI made by a covered entity in the 6 years prior to the date on which the accounting is required, except for disclosures: (i) to carry out treatment, payment, and health care operations; (ii) to individuals of PHI about them; (iii) for the facility's directory or to persons involved in the individual's care or other notification purposes; (iv) for national security or intelligence purposes; (v) to correctional institutions or law enforcement officials; or (vi) which occurred prior to the compliance date for the covered entity. (b)(2) Content of the accounting: For each disclosure, the accounting must include: (i) date of disclosure; (ii) name and, if known, address of the recipient of the PHI; (iii) brief description of the PHI disclosed; (iv) brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure. If, during the period of the accounting, the covered entity has made multiple disclosures of PHI to the same person or entity for a single purpose pursuant to and in compliance with a valid consent under HIPAA or where a consent, authorization, or an opportunity to agree or object is not required, the accounting may provide: (i) the information required to be included in the accounting for the first disclosure during the accounting period; (ii) the frequency, periodicity or number of the disclosures made during the accounting period and (iii) the date of the last disclosure during such accounting period.</p>	<p><u>Preempted in Part:</u> With regard to limitations on disclosures, State law is more restrictive and therefore applies.</p> <p>State law requires a notation be made of disclosures in the patient record, except for disclosures that can be characterized as those for treatment, payment, or health care operations purposes. This is consistent with HIPAA, and thus State law applies. State law also requires that patients be informed of disclosures upon request, which is also consistent with HIPAA. However, HIPAA preempts some aspects of State law with regard to the necessary content in accountings of disclosures, since the Federal regulations go further in specifying the information that must be included in the accounting.</p>
<p>Facility Directories</p> <p>May be addressed in individual NYS OMH facility policies.</p>	<p>§164.510(a): A health care provider that is a covered entity may, if the patient has been given advance notice of the use/disclosure and has been given the opportunity to agree/object to the disclosure, use/disclose the following PHI to maintain a directory of patients: (A) name; (B) location in the facility;(C)condition, described in general terms; (D) religious affiliation...and may disclose such information; (A) to members of the clergy; or (B) except for religious affiliation, to others who ask for the patient by name.</p>	<p>If such disclosures are consistent with State policy, HIPAA would permit disclosures for facility directories; HIPAA opportunity to agree and object requirements prevail.</p>
<p>Disaster Relief</p>	<p>§164.510(b)(4): A covered entity may use/disclose PHI to a public/private entity</p>	<p>If such disclosures are consistent with</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
Not specifically addressed in NYS Mental Hygiene Law	authorized by law or by its charter to assist in disaster relief effort.	State policy, HIPAA would permit disclosures for disaster relief purposes.
Cadaveric, Organ, Eye or Tissue Donation Not specifically addressed in NYS Mental Hygiene Law (Note: will be addressed in pending OMH Official Policy PC-450; Patient Death, but disclosures will be required to be in concert with state and federal law and regulations)	§164.512(h): A covered entity may use/disclose PHI to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation.	If such disclosures are consistent with State policy, HIPAA will govern these disclosures as there is not comparable provision of State law.
Military and Veteran Activities Not specifically addressed in NYS Mental Hygiene Law	§164.512(k)(1): Requirements for uses/disclosures by covered entities regarding Armed Forces personnel, discharge or separation from military service, veterans, and foreign military personnel are detailed in this section.	If such disclosures are consistent with State policy, HIPAA will govern these disclosures as there is not comparable provision of State law.
National Security and Intelligence Activities Not specifically addressed in NYS Mental Hygiene Law	§164.512(k)(2) A covered entity may disclose PHI to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other authorized security activities.	If such disclosures are consistent with State policy, HIPAA will govern these disclosures as there is not comparable provision of State law.
Protective Services for the President and Others Not specifically addressed in NYS Mental Hygiene Law	§164.512(k)(3) A covered entity may disclose PHI to authorized federal officials for the provision of protective services to the President or other authorized persons.	If such disclosures are consistent with State policy, HIPAA will govern these disclosures as there is not comparable provision of State law.
Medical Suitability Determination Not specifically addressed in NYS Mental Hygiene Law	§164.512(k)(4): A covered entity that is a component of the State may use PHI for this purpose, as governed by this section.	If such disclosures are consistent with State policy HIPAA will govern these disclosures as there is not comparable provision of State law.
Workers' Compensation Not specifically addressed in NYS Mental Hygiene Law	§164.512(k)(7): A covered entity may disclose PHI as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.	<u>No Preemption:</u> As disclosures under this section are to be "as authorized by law," HIPAA and any governing State law will, by operation, be consistent.
MHL SECTION 33.16 - ACCESS TO CLINICAL RECORDS		
Definitions	§164.501: "Designated Record Set" means: (1) A group of records maintained by	<u>No Preemption:</u> State law and Federal

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>MHL §33.16(a)(1): <i>Clinical record</i> means any information concerning or relating to the examination or treatment of an identifiable patient or client maintained or possessed by a facility which has treated or is treating such patient or client, except data disclosed to a practitioner in confidence by other persons on the express condition that such data would never be disclosed to the patient or client or other persons, provided that such data has never been disclosed by the practitioner or a facility to any other person. If at any time such data is disclosed (unless the disclosure is made pursuant to MHL §33.13, to practitioners as part of consultation or referral, to the statewide planning and research cooperative system, or to the committee or a court pursuant to MHL §33.16, or to an insurance carrier insuring, or an attorney consulted by, a facility) it is considered clinical records.</p>	<p>or for a covered entity that is:(i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.</p> <p>(2) ...the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.</p> <p>§164.524(a)(2)(v): an individual's access may be denied if the PHI was obtained from someone other than a health care provider under a promise of confidentiality...."</p> <p>§164.524(a)(1) excludes the following from access by an individual:</p> <p>(i) Psychotherapy notes;</p> <p>(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and</p> <p>(iii) Protected health information maintained by a covered entity that is:</p> <p>(A) Subject to the Clinical Laboratory Improvements Amendments of 1988 to the extent the provision of access to the individual would be prohibited by law; or</p> <p>(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988.</p> <p>65 Fed. Reg. 82605, 82606 (December 28, 2000): peer review or other quality assurance files which are used only to improve patient care at the facility, and not to make decisions about individuals, are not part of that facility's "designated record set."</p>	<p>law are generally consistent.</p>
<p>Definitions</p> <p>MHL §33.16(a)(5): <i>Patient or client</i> means an individual concerning whom a clinical record is maintained or possessed by a facility as defined in paragraph 3 of this subdivision.</p>	<p>§164.501: "<i>Individual</i>" means the person who is the subject of protected health information</p>	<p><u>No preemption:</u> State law is not contrary to HIPAA; laws are similar; State law prevails.</p>
<p>Definitions</p> <p>MHL §33.16(a)(6): <i>Qualified person</i> means (1) any properly identified patient or client; (2) guardian of a mentally retarded or developmentally disabled person; (3) committee for an incompetent; (4) parent of an infant; (5) guardian of an infant; or (6) a parent, spouse, or adult child of an adult patient or client who may be entitled to request access to a clinical record pursuant to MHL §33.16(b)(4).</p>	<p>§164.501: "<i>Individual</i>" means the person who is the subject of protected health information.</p> <p>§164.502(g) (1) :A "personal representative" can fulfill the role of the individual about whom PHI pertains; (2) If, under applicable law, a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative with respect to PHI relevant to such personal representation.</p>	<p><u>No preemption:</u> State law is not contrary to HIPAA; laws are similar; State law prevails.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Access by Qualified Persons MHL §33.16(b)(1): Upon the written request of any patient/client (or other qualified person) a facility shall provide an opportunity within 10 days for that individual to inspect any clinical record concerning or relating to the examination or treatment of that individual in the possession of such facility (subject to applicable access conditions or limitations)</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(b)(2): The covered entity must act on a request for access no later than 30 days after receipt of the request.</p>	<p><u>Preempted in Part:</u></p> <ol style="list-style-type: none"> 1. With regard to the type of information for which a patient can request access, State law and HIPAA are similar. 2. State law prevails with regard to timelines in which a covered entity must act on a request for access; State law requires that such action within a 10 day period and HIPAA permits 30 days; thus, State law prevails here. 3. State law does not include a requirement for patients to be advised of the need to make written requests for access; HIPAA prevails in this regard. 4. State law is more stringent than HIPAA in that it does not limit access to psychotherapy notes; however, it must be noted, that in the State operated and licensed NYS mental health system, the presence of any information that would constitute "psychotherapy notes" does not, as a practical matter, exist since by regulation, all information from which decisions are to be made about a patient must be included in the patient's clinical record.
<p>Access by Qualified Persons MHL §33.16(b)(2): Upon the written request of a committee for an incompetent or guardian of the person of a mentally retarded or developmentally disabled person a facility shall provide an opportunity within 10 days for that individual to inspect any clinical record concerning or relating to the examination or treatment of that individual in the possession of such facility. Provided, however, in the case of any guardian to inspect the clinical record concerning a client 18 years of age or older, the facility shall notify the client of such</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(b)(2): The covered entity must act on a request for access no later than 30 days after receipt of the request.</p>	<p><u>Preempted in Part:</u></p> <ol style="list-style-type: none"> 1. With regard to the type of information for which a committee/guardian can request access, State law and HIPAA are similar. 2. State law prevails with regard to timelines in which a covered entity must act on a request for access; State law requires that such action within a 10 day period and HIPAA permits 30 days;

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
request.		<p>thus, State law prevails here.</p> <p>3. State law does not include a requirement for patients to be advised of the need to make written requests for access; HIPAA prevails in this regard.</p> <p>4. HIPAA does not require an individual be notified if a personal representative requests access to his/her record; State law does. In this regard, State law is more stringent and thus prevails.</p> <p>5. State law is more stringent than HIPAA in that it does not limit access to psychotherapy notes; however, it must be noted, that in the State operated and licensed NYS mental health system, the presence of any information that would constitute "psychotherapy notes" does not, as a practical matter, exist since by regulation, all information from which decisions are to be made about a patient must be included in the patient's clinical record.</p>
<p>Access by Qualified Persons MHL §33.16(b)(3): Upon the written request of a parent of an infant or guardian of an infant.... a facility shall provide an opportunity within 10 days for that individual to inspect any clinical record concerning or relating to the examination or treatment of that individual in the possession of such facility. Provided, however, that such parent or guardian shall not be entitled to inspect or make copies of any clinical record concerning the care and treatment of an infant where the treating practitioner determines that access to the information requested by such person would have a detrimental effect on the practitioner's professional relationship with the infant, or the care and treatment of the infant or on the</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(b)(2): The covered entity must act on a request for access no later than 30 days after receipt of the request.</p> <p>§164.524(a)(3)(iii) A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed in the following circumstances: (iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.</p>	<p><u>Preempted in Part:</u></p> <p>1. With regard to the type of information for which a parent/guardian of an infant can request access, State law and HIPAA are similar.</p> <p>2. State law prevails with regard to timelines in which a covered entity must act on a request for access; State law requires that such action within a 10 day period and HIPAA permits 30 days; thus, State law prevails here.</p> <p>3. State law does not include a requirement for patients to be advised of the need to make written requests for access; HIPAA prevails in this regard.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>infant's relationship with his/her parent or guardian.</p>		<p>4. State law and HIPAA are consistent in that both permit denial of access in the case of likelihood to cause harm to the individual or another person. State law permits review of such denials via MHL §33.16 (c)(4). Hence, State law is not contrary to HIPAA and State law prevails.</p> <p>5. State law is more stringent than HIPAA in that it does not limit access to psychotherapy notes; however, it must be noted, that in the State operated and licensed NYS mental health system, the presence of any information that would constitute "psychotherapy notes" does not, as a practical matter, exist since by regulation, all information from which decisions are to be made about a patient must be included in the patient's clinical record.</p>
<p>Access by Qualified Persons MHL §33.16(b)(4): Upon the written request of a parent of an adult patient, or spouse or adult child of a patient,.... a facility shall provide an opportunity within 10 days for that individual to inspect any clinical record concerning or relating to the examination or treatment of that individual, which the parent, spouse or child is authorized by law to provide consent or is being requested to provide such consent, in the possession of such facility. Provided, however, that such parent, spouse, or child shall not be entitled to inspect or make copies of any clinical record concerning the care and treatment of an individual where the treating practitioner determines that access to the information requested by such person would have a detrimental effect on the practitioner's professional relationship with the individual, or the care and treatment of the individual or on the individual's relationship with his/her parent, spouse, or child. Any inspection shall be</p>	<p>§164.502(g) (1) :A "personal representative" can fulfill the role of the individual about whom PHI pertains; (2) If, under applicable law, a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative with respect to PHI relevant to such personal representation.</p> <p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(b)(2): The covered entity must act on a request for access no later than 30 days after receipt of the request.</p> <p>§164.524(a)(3)(iii) A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed in the following circumstances: (iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or</p>	<p><u>Preempted in Part:</u></p> <p>1. With regard to the type of information for which a parent, spouse, child can request access, State law and HIPAA are similar.</p> <p>2. State law prevails with regard to timelines in which a covered entity must act on a request for access; State law requires that such action within a 10 day period and HIPAA permits 30 days; thus, State law prevails here.</p> <p>3. HIPAA and State law are consistent in terms of permitting parents of adult patients, or their spouse or adult child to request access in that State law only permits such access if such person is authorized by law to consent to treatment (i.e., is authorized to make health care decisions for the individual, as is required by HIPAA).</p> <p>4. State law and HIPAA are consistent in that both permit denial of access in</p>

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<p>limited to that information which is relevant in light of the reason for such inspection.</p>	<p>another person.</p>	<p>the case of likelihood to cause harm to the individual or another person. State law permits review of such denials via MHL §33.16 (c)(4). Hence, State law is not contrary to HIPAA and State law prevails.</p> <p>5. HIPAA does not limit access to records by personal representatives to that which is relevant in light of the reason for inspection, as does State law in this subdivision. HIPAA indicates that for purposes of access, personal representatives “stand in the shoes” of individuals; therefore, it is reasonable to conclude that to the extent that a personal representative is requesting disclosure of information on behalf of a patient, and for the same purpose and to the same extent that the patient would do so, State law and HIPAA are consistent and State law prevails.</p> <p>6. State law is more stringent than HIPAA in that it does not limit access to psychotherapy notes; however, it must be noted, that in the State operated and licensed NYS mental health system, the presence of any information that would constitute “psychotherapy notes” does not, as a practical matter, exist since by regulation, all information from which decisions are to be made about a patient must be included in the patient’s clinical record.</p>
<p>Access by Qualified Persons MHL §33.16(b)(5) A facility shall furnish, upon the written request of a qualified person, within a reasonable time, a copy of any clinical record requested which the person is authorized to inspect.</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(c)(1): The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the PHI about them in designated record sets.</p>	<p><u>Preempted in Part:</u></p> <p>1. As a technical matter, State law is actually more stringent on its face since it does not limit access to psychotherapy notes; however, it must be noted, that in the State operated and licensed NYS mental health system, the presence of any information that</p>

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	<p>(c)(2)(i): The covered entity must provide the individual with access to the PHI in the form or format requested by the individual, if it is readily producible in such form or format; if not, a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.</p>	<p>would constitute "psychotherapy notes" does not, as a practical matter, exist since by regulation, all information from which decisions are to be made about a patient must be included in the patient's clinical record.</p> <p>2. Unless the facility has previously notified the qualified person that his/her request for access must be in writing, restricting actionable requests to written ones is contrary to HIPAA; hence this provision of State law would be preempted.</p> <p>3. State law provisions which leave as the only option for providing access as via a copy of the information is inconsistent with HIPAA's provisions authorizing individuals to dictate the form or format of their PHI, if readily producible as such. Therefore, this provision of HIPAA also prevails.</p>
<p>Access by Qualified Persons MHL §33.16(b)(6) (a) The facility may impose a reasonable charge for all inspections and copies; i.e., a maximum of 75 ¢ per page. A qualified person shall not be denied access to the clinical record solely because of inability to pay. (b) ...for copies requested by an attorney or another person or insurer representing or acting on behalf of the patient or his/her estate, the provider may impose a reasonable charge for all inspections and copies, not to exceed the costs incurred by such provider, however, the reasonable charge for paper copies shall not exceed \$1 per page for paper copies and \$2 per page for microfilm or microfiche copies.</p>	<p>§164.524(c)(4): The covered entity may impose a reasonable, cost based fee, provided that the fee only includes the cost of: (i) copying, cost of supplies and labor of copying; (ii) postage, when requested by the individual to be mailed to him/her; (iii) preparing an explanation or summary of the PHI, if agreed to by the individual.</p>	<p><u>No Preemption:</u> State law is more stringent than HIPAA; first, the fee imposed by State law, is reasonably related to the costs permitted by HIPAA and probably is less than the amount HIPAA would ultimately permit for copies, postage, and preparing an explanation/summary (it should be noted that HIPAA does not expressly permit charging for "inspections," as is literally provided in State law, but as a matter of standard practice, the basis for this charge is copying and postage; hence, it is reasonable to interpret these provisions as consistent). Second, State law's provision prohibiting denial of access solely due to inability to pay provides more rights to the individual and hence is more</p>

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		stringent than HIPAA. HIPAA does not address fees that can be assessed on attorneys or another person or insurer acting on behalf of the patient or his/her estate (i.e. those who are not personal representatives).
<p>Access by Qualified Persons MHL §33.16(b)(7)</p> <p>A facility may place reasonable limitations on the time, place, and frequency of any inspection of clinical records.</p>	<p>§164.524(c)(3): Time and manner of access. The covered entity must provide the access as requested by the individual in a timely mannerincluding arranging with the individual for a convenient time and place to inspect or obtain a copy of the PHI or mailing a copy of the PHI at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.</p>	<p><u>State Law Preempted:</u> While State law and HIPAA are similar, HIPAA requires the covered entity to discuss with the individual a convenient time and place for access. This step is not required in State law and must be before a facility is authorized to place reasonable time, place, and frequency conditions on access.</p>
<p>Access by Qualified Persons MHL §33.16(b)(8)</p> <p>A treating practitioner may request the opportunity to review the patient information with the qualified person requesting such information, but such review shall not be a prerequisite for furnishing the record.</p>	<p>§164.524(c)(3):The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.</p>	<p><u>No Preemption</u> State law is not contrary to HIPAA; State law prevails.</p>
<p>Access by Qualified Persons MHL §33.16(b)(9): A facility may make available for inspection either the original or a copy of the clinical records.</p>	<p>§164.524(c)(1): The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the PHI about them in designated record sets...</p> <p>(c)(2)(i): The covered entity must provide the individual with access to the PHI in the form or format requested by the individual, if it is readily producible in such form or format; if not, a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.</p>	<p><u>State Law Preempted:</u> With regard to the requirement to make either originals or copies available to individuals, State law and HIPAA are generally similar. However, State law <u>permits</u> facilities to make available for the inspection <u>either</u> the original or a copy; HIPAA <u>requires</u> covered entities to provide the access by inspection (of presumably originals) or by providing copies, <u>or both</u>.</p> <p>Additionally, State law is silent with regard to authorizing individuals to dictate the form or format of their PHI, if readily producible as such. Therefore, this provision of HIPAA also prevails.</p>
<p>Limitations on Access</p>	<p>§164.524(a)(2): <i>Unreviewable grounds for denial.</i> A covered entity may deny</p>	<p><u>Fact Dependent:</u> To the extent that the</p>

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<p>MHL §33.16(c)(1): Upon the written request by a qualified person to inspect or copy the clinical record maintained by a facility, the facility shall inform the treating practitioner of the request. The treating practitioner may review the information requested. Unless the treating practitioner determines that the requested review of the clinical record can reasonably be expected to cause substantial and identifiable harm to the patient or others that would outweigh the qualified person's right of access, review of such record shall be permitted or copies provided.</p>	<p>access to an individual without providing the individual an opportunity for review if: (1) the PHI is excepted from the right of access; (2) the individual consented to have the right of access temporarily suspended in the course of research that includes treatment; (3) information is protected under the Privacy Act; or (4) the information was obtained from someone other than the health care provider under a promise of confidentiality and the access requested would likely reveal the source of the information.</p> <p>§164.524(a)(3) Reviewable grounds for denial: A covered entity may deny an individual access, but must be given a right to have such denials reviewed in 3 circumstances (i) when access would be reasonably likely to endanger the life or physical safety of the individual or another person; (ii) when the PHI makes reference to another person and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or (iii) the request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.</p> <p><i>re: (a)(3)(iii) Preamble:</i> Under this reason for denial, covered entities may not deny access on the basis of the sensitivity of the health information or the potential for causing emotional or psychological harm.</p>	<p>qualified person is a parent or guardian of an infant, or a parent, spouse, or adult child of an adult patient who is authorized by law to make health decisions for the patient, State law is not preempted. To the extent, however, that the request is being made by the patient and there is no possibility of a threat to the life or physical safety of the patient or others, HIPAA is more stringent than State law in that it provides a greater right of access to the patient. Hence, in this circumstance, State law would be preempted.</p>
<p>Limitations on Access MHL §33.16(c)(2): A patient over the age of 12 may be notified of any request by a qualified person to review his/her record and if the patient objects to disclosure, the facility, in consultation with the practitioner, may deny the request.</p>	<p>No comparable provision.</p>	<p><u>No Preemption:</u> Although HIPAA indicates that for purposes of access, personal representatives "stand in the shoes" of individuals, it is reasonable to conclude that State law actually protects the privacy of an <u>individual's</u> records by providing an opportunity for a minor patient to limit what can be disclosed to a greater degree than does HIPAA ; hence, State law is more stringent and should prevail.</p>
<p>Limitations on Access MHL §33.16(c)(3): If, after consideration of all the attendant facts and circumstances, the practitioner/treating practitioner determines that the requested review of all or part of the clinical record can reasonably be expected to cause</p>	<p>§164.524(a)(2): Unreviewable grounds for denial. A covered entity may deny access to an individual without providing the individual an opportunity for review if: (1) the PHI is excepted from the right of access; (2) the covered entity is a correctional institution, the requestor is an inmate, and his/her access to PHI would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee or other person at the</p>	<p><u>Fact Dependent:</u></p> <p>1. In cases where HIPAA would allow a denial of access yet State law permits a summary rather than a complete denial, State law is more stringent and</p>

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<p>substantial and identifiable harm to the patient or others, or would have a detrimental effect, the facility may deny access to all or part of the record and may grant access to a prepared summary of the record. In making such determination, the practitioner/treating practitioner may consider, among other things, the following: (1) the need for, and the fact of, continuing care & treatment; (2) the extent to which the knowledge of the information contained in the clinical record may be harmful to the health and safety of the patient or others; (3) the extent to which the clinical record contains sensitive information disclosed in confidence to the practitioner/treating practitioner by family members, friends, and other persons, (4) the extent to which the clinical record contains sensitive information disclosed in confidence to the practitioner/treating practitioner by the patient which would be injurious to the patient's relationships with other persons except where the patient is requesting information about him/herself; and (5) in the case of a minor making a request for access, the age of the patient.</p>	<p>correctional institution or responsible for the transport of the inmate; (3) the individual consented to have the right of access temporarily suspended in the course of research that includes treatment; (4) information is protected under the Privacy Act; or (5) the information was obtained from someone other than the health care provider under a promise of confidentiality and the access requested would likely reveal the source of the information.</p> <p>§164.524(a)(3) Reviewable grounds for denial: A covered entity may deny an individual access, but must be given a right to have such denials reviewed in 3 circumstances (i) when access would be reasonably likely to endanger the life or physical safety of the individual or another person; (ii) when the PHI makes reference to another person and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or (iii) the request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.</p> <p><i>re: (a)(3)(iii) Preamble:</i> Under this reason for denial, covered entities may not deny access on the basis of the sensitivity of the health information or the potential for causing emotional or psychological harm.</p>	<p>prevails.</p> <p>2. To the extent that the qualified person is a parent or guardian of an infant, or a parent, spouse, or adult child of an adult patient who is authorized by law to make health decisions for the patient State law is not preempted.</p> <p>3. However, to the extent that the request is being made by the patient and there is no possibility of a threat to the life or physical safety of the patient or others, (unless the patient is an inmate, e.g., a person committed to a psychiatric institution via criminal court order) HIPAA is more stringent than State law in that it provides a greater right of access to the patient. Hence, in this circumstance, State law would be preempted.</p> <p><i>*Note:</i> In cases where a treating practitioner/practitioner believes there is a substantial threat to the emotional health of the patient, it would not be contrary to HIPAA if the patient consents to waive access to certain parts of, or temporarily delay his/her access, to the records.</p>
<p>Limitations on Access MHL §33.16(c)(4): In the event of a denial of access, the qualified person shall be informed by the facility of such denial, and of the qualified person's right to obtain, without cost, a review of the denial by the appropriate clinical record access review committee.</p> <p>If such a review is requested, the facility will, within 10 days of its receipt thereof, transmit the record to the chairman of the appropriate</p>	<p>§164.524(d)(2): The covered entity must provide a timely, written denial to the individual. The denial must be in plain language and contain: (i) the basis for the denial; (ii) a statement of the individual's rights, including a description of how the individual may exercise such review rights; and (iii) a description of how the individual may complain to the covered entity. The description must include the name, or title, and telephone number of the contact person or office designated in §160.530(a)(1)(ii).</p> <p>§164.524(d)(4): If the individual has requested a review of a denial, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The</p>	<p><u>No Preemption:</u></p> <p>1. Under State law, review is done without cost to the patient; HIPAA is silent on this point. As to this provision, State law prevails as it provides more rights/greater access to PHI to the individual.</p> <p>2. State law is more stringent with regard to putting a time limit of 10 days within which to facilitate review; HIPAA</p>

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<p>committee with a statement indicating why access was denied. After an in camera review, and after providing all parties an opportunity to be heard, the committee shall promptly make a determination whether review of the records is likely to cause substantial and identifiable harm to the patient or others which outweighs the qualified person's right of access, or whether the requested review would have a detrimental effect (as defined in subdivision (b) of this section). If the committee determines the request for access should be granted, the committee shall notify all parties and the access shall be granted.</p>	<p>designating reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required to carry out the designated reviewing official's determination.</p>	<p>merely sets a general obligation to do so "promptly." Hence, State law prevails here.</p> <p>3. State law provisions which require that the information and a statement setting forth the reasons why access was denied permit the reviewing entity to be privy to a greater pool of information than does HIPAA, which merely requires that the request be referred. Furthermore, State law allows all parties to be heard and requires in camera review of materials; HIPAA is silent with regard to due process requirements. These provisions could facilitate an individual's greater access to information, and therefore these State law provisions prevail.</p> <p>4. State law requires that a written decision by the review committee be given promptly. HIPAA indicates the decision must be given in a reasonable period of time, and does not indicate the decision must be given in writing. While HIPAA indicates the individual is to be promptly notified of the decision and State law is silent on this point, the requirement for the written decision to be "given promptly," can reasonably be interpreted to mean that the individual is to be promptly notified. Therefore, these provisions do not appear inconsistent and State law is not preempted.</p> <p>5. HIPAA requires that the individual be notified of the decision; State law requires all parties to be so notified. Inasmuch as it is possible for a covered entity to comply with both provisions, State law is not preempted.</p>

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		<p>6. State law requires that if access is granted, the provider must grant access. HIPAA required the covered entity to take action to carry out the determination; these provisions are consistent and State law is not preempted.</p>
<p>Limitations on Access MHL §33.16(c)(5): If, after review by the clinical access committee, access is denied in whole or part, the committee shall notify the person of his/her right to seek judicial review of the determination. Within 30 days of receiving notification of the decision, the qualified person may commence, upon notice, a special proceeding in supreme court for a judgment requiring the provider to make the record available for inspection/copying. The court, upon such application and in camera review (including the determination and record of the committee), and after providing all parties an opportunity to be heard, shall determine if a reasonable basis exists for denial of access. The relief shall be limited to a judgment requiring the facility to make the records available to the qualified person for inspection/copying.</p>	<p>No corresponding provision.</p>	<p><u>No preemption:</u> HIPAA does not provide for a second level of review, as is so provided in State law. As such, State law is more stringent in that it provides greater access by giving a person a second opportunity to be granted access on review.</p>
<p>Clinical Records Access Review Committees MHL §33.16(d): The Commissioners of OMH, OMRDD, and OASAS must appoint clinical record access review committees to hear appeals of the denial of access to patient records as provided for in subdivision (c) of this section. Members of the committees must be appointed by the respective Commissioners. The Committees shall consist of no fewer than</p>	<p>§164.524(d)(4): If the individual has requested a review of a denial, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designating reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required to carry out the designated reviewing official's determination.</p>	<p><u>Fact Dependent:</u> State law does not specify the qualifications of members of the Clinical Access Review Committees, while HIPAA requires a "licensed health professional" to review denials of access. Compliance with both laws could be effected if at least one of the members appointed by a Commissioner for his Clinical Access Review Committee be a licensed health</p>

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<p>3, nor no more than 5, persons. The Commissioners must promulgate rules and regulations to effect this section.</p> <p>14 NYCRR §633.4(a)(10)(ii): The Clinical Access Review Committee shall consist of an OMRDD attorney; an OMRDD practitioner, and a representative of the voluntary provider agency community. The chairperson shall be an OMRDD attorney, and requests for review of denial of access shall be addressed to the Office of Counsel for OMRDD.</p>		<p>professional.</p> <p>Note, however, that OMRDD regulations are preempted by HIPAA because its specification of the composition of its Clinical Access Review Committees is inconsistent with HIPAA. OMH and OASAS may wish to develop regulations which properly reflect HIPAA to ensure State law is consistently interpreted.</p>
<p>Applicability of federal law MHL §33.16(f): Whenever federal law or applicable federal regulations restrict, or as a condition of federal aid require, that the release of clinical records or information be more restrictive than is provided under this section, the provisions of federal law or federal regulation shall be controlling.</p>	<p>§160.203: This general rule applies, except if one or more of the following conditions is met:....2) the provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification under the Federal Rule.</p>	<p><u>No Preemption:</u> HIPAA preempts State laws that are more stringent with regard to disclosure, including those that would more greatly restrict patient access to PHI; State law indicates it is preempted by federal law and regulations that are more restrictive in terms of disclosures. Therefore, State law and the HIPAA Privacy regulation are generally consistent with regard to disclosures of PHI.</p>
<p>Challenges to accuracy MHL §33.16(g): A qualified person may challenge the accuracy of information maintained in the clinical record and may require that a brief written statement prepared by him/her concerning the challenged information be inserted into the clinical record. This statement shall become a permanent part of the record and shall be released whenever the clinical record at issue is released. This subdivision shall apply only to factual statements and shall not include a provider's observations, inferences or conclusions. A facility may place reasonable restrictions on the time and frequency of any challenges to accuracy.</p>	<p>§164.501: "Designated Record Set" means: (1) A group of records maintained by or for a covered entity that is:(i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) ...the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.</p> <p>§164.526(a)(1),(2): (1) An individual has the right to have a covered entity amend PHI or a record about the individual in a designated record set for as long as the PHI is maintained in the designated record set.</p> <p>(2) Denial of amendment. A covered entity may deny an individual's request for amendment if it determines the PHI or record...(1) was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of the PHI is no longer available to act on the requested amendment; (2) is not part of the designated record set; (3) would not be available for inspection</p>	<p><u>Preempted in Part:</u></p> <p>1. <i>Right to amend:</i> Not preempted. A State law would be preempted if more greatly restricted the right of amendment than does HIPAA. The State statute permits challenges to accuracy by "qualified persons," similar to the HIPAA provisions permitting amendment by "individuals," which term includes "personal representatives." Further, both laws permit "appending" to records, rather than deleting/correcting records. State law ensures the amended information is protected to the same degree as the clinical record, consistent with HIPAA provisions. Under State law, "challenging the accuracy of</p>

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	<p>under the access provision; or (4) is accurate and complete.</p> <p><i>Preamble:</i> Many commenters strongly encouraged the Secretary to adopt "appendment" rather than "amendment and correction" procedures. They argued that the term "correction" implies a deletion of information....appendment rather than correction procedures will ensure the integrity of the medical record and allow subsequent health care providers access to the original information as well as the appended information.....We agree.....we have revised the rule..in order to clarify that covered entities are not required by this rule to delete any information from the designated record set. We do not intend to alter medical record retention laws or current practice, except to require covered entities to append information as requested to ensure that a record is accurate and complete. (p. 82736:1)</p>	<p>information" is the functional equivalent of amending.</p> <p>2. <i>Timely action by covered entity:</i> State law does not contain time requirements for responding to requests for amendment/challenge to accuracy. Therefore, the time requirements in HIPAA should be referred to as an outside parameter within which a response should be provided.</p> <p>3. <i>Making the amendment.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>4. <i>Informing the individual.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>5. <i>Informing others.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>6. <i>Denial.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>7. <i>Statement of disagreement.</i> State law contains no comparable provisions regarding statements of disagreement with amendment denials; hence, HIPAA applies.</p> <p>8. <i>Rebuttal Statement.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>9. <i>Recordkeeping.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>10. <i>Future Disclosures:</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>11. <i>Actions on Notices of Amendments.</i> State law contains no comparable provisions; hence, HIPAA applies.</p> <p>12. <i>Documentation:</i> State law contains no comparable provisions; hence, HIPAA applies.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
No comparable provisions.	<p>§164.526(b)(2) Timely action by covered entity. The covered entity must act on the individual's request no later than 60 days after receipt of such request by either taking the required action if it grants or denies the request in whole or in part. If the covered entity is unable to act on the amendment within the time required, the covered entity may have a one time extension of time for such action of no more than 30 days, provided that it provides the individual with a written statement of the reason for the delay and the date by which the covered entity will complete its action.</p> <p>§164.526(c)(1): Making the amendment. The covered entity must make the appropriate amendment to the PHI or record that is the subject of the request, by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.</p> <p>§164.526(c)(2): Informing the individual. The covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify relevant persons with whom the amendment needs to be shared.</p> <p>§164.526(c)(3): Informing others. The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to persons identified by the individual as having received PHI about the individual and needing the amendment, and persons, including business associates, that the covered entity knows have the PHI which is the subject of the amendment and that may have relied or could foreseeably rely, on such information to the detriment of the individual.</p> <p>§164.526(d)(1): Denial. The covered entity must provide the individual with a timely, written denial. The denial must be in plain language and contain: (1) the basis for the denial, (2) the individual's right to submit a written statement of disagreement, and how to file such a statement; (3) a statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the PHI; and (4) the covered entity's complaint procedures or how to file a complaint with the Secretary under HIPAA.</p> <p>§164.526(d)(2): Statement of disagreement: The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement or disagreement.</p> <p>§164.526(d)(3) Rebuttal statement. The covered entity may prepare a written rebuttal to the individual's statement of disagreement and provide a copy of such written rebuttal to the individual.</p> <p>§164.526(d)(4): Recordkeeping. The covered entity must, as appropriate, identify the record or PHI in the designated record set that is the subject of the disputed</p>	

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>amendment and append or otherwise link the individual's request for an amendment, the denial of the request, the statement of disagreement, if any, and the rebuttal statement, if any, to the designated record set.</p> <p>§164.526(d)(5) Future disclosures. If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended, or at the election of the covered entity, a summary of any such information, with any subsequent disclosure of the PHI to which the disagreement relates. If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with subsequent disclosure of the PHI only if the individual has properly requested such action. When a subsequent disclosure is made using a standard transaction (as defined in 45 CFR Part 162) that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required, as applicable, to the recipient of the standard transaction.</p> <p>§164.526(e) Actions on Notices of Amendments. A covered entity that is informed by another covered entity of an amendment to the individual's PHI must amend the individual's PHI in the designated record set.</p> <p>§164.526(f): Documentation. A covered entity must document titles of the persons/offices responsible for receiving and processing requests for amendments by individuals and retain the documentation according to the requirements of HIPAA.</p>	
<p>Disclosure MHL §33.16(i): Nothing contained in this section shall restrict, expand, or in any way limit the disclosure of any information pursuant to articles 23, 31, and 45 of the Civil Practice Law and Rules or Section 677 of the County Law.</p>	<p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814: 3)</p> <p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p>	<p><u>No Preemption</u>: There is no comparable provision in HIPAA; disclosures permitted under laws cross-referenced in this section are individually permitted via the listed exceptions in HIPAA, or because the disclosures are being made by non-covered entities.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
MHL SECTION 33.21 Consent for Mental Health Treatment of Minors		
<p>MHL §33.21: (b) In providing outpatient mental health services to a minor..... the important role of parents or guardians shall be recognized....and the consent of such persons shall be required for such treatment in non-emergency situations, except as provided in subdivisions (c),(d), and (e) of this section or section 2504 of the Public Health Law.</p> <p>(c) ...The mental health practitioner shall fully document the reasons for his/her determinations. Such documentation shall be included in the minor's clinical record....As clinically appropriate, notice of a determination made pursuant to subparagraph (iii) of paragraph 3 of this subdivision shall be provided to the parent/guardian.</p>	<p>Not originally addressed in final rule; but Recently Adopted Amendments:</p> <p>§164.502: (g)(1)(ii) Implementation specification: unemancipated minors...(A).A covered entity may disclose PHI about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> if the applicable provision of State law or other law, including applicable case law, permits or requires such disclosure, and (B) a covered entity may not disclose PHI about about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> if the applicable provision of State law or other law, including applicable case law, prohibits such disclosure.</p>	<p><u>No Preemption:</u> Recent adoption of the amendments to HIPAA defer to State law with regard to parental consent/access to records of minors, therefore, State law controls.</p>
MHLSECTION 43.05: Investigations/Patient Resources		
<p>MHL §43.05 Disclosure of the fact of the patient's hospitalization in connection with an investigation of the patient's resources is permitted but requires release of patient.</p>	<p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	<p><u>No Preemption.</u> Recent amendments to HIPAA remove the need to obtain consent to use/disclose PHI for payment purposes. State law , however,requires patient consent to investigate resources for payment purposes, which is more stringent than HIPAA. Hence, State law prevails.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>MHL ARTICLE 45: Commission on Quality of Care for the Mentally Disabled</p>		
<p>MHL §45.09: Procedures of the commission. (a) The commission, any member or any employee designated by the commission, must be granted access at any and all times to any mental hygiene facility, or adult home or residence for adults in which 25% or more residents have at any time received or are receiving services from a mental hygiene provider which is licensed, funded, or operated by OMH or OMRDD in order to carry out the functions of the commission as provided for in section 45.10 of this article, ...and to all books, records, and data pertaining to any such facility deemed necessary for carrying out the commission's functions, powers and duties....The Commission or any member may require from any hospital, as defined under Article 28 of the Public Health Law, any information, report, or record necessary for the purpose of carrying out the functions, powers and duties of the commission related to the investigation of deaths and complaints of abuse or mistreatment concerning patients or former patients of mental hygiene facilities who have been treated at such hospitals, and from any adult care facility....such information, report or record, including access to such facility necessary for the purpose of carrying out the functions, powers and duties of the commission related to the investigation of deaths, as provided for by section 45.17 of this chapter.... The results of investigations involving such residents of adult care facilities shall be provided promptly to the commissioner of the department of social services and shall be treated as a record or personal information within the meaning of section 96 of the Public Officers Law and shall not be disclosed except in accordance with such section 96. Information, books, records or data which are confidential as provided by law shall be kept</p>	<p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid under this section. (p. 82811:1)</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(d): PHI can be released to health oversight agencies for oversight activities authorized by law, including administrative investigations.</p>	<p><u>No Preemption:</u> The CQC meets the definition of a "health oversight agency" under HIPAA. As such:</p> <ol style="list-style-type: none"> 1. Disclosures by covered entities to CQC are permitted under the "health oversight exception" to HIPAA. 2. Assuming the CQC is not a covered entity (as it is neither a health plan, health care clearinghouse, or health care provider engaging in electronic transactions), disclosures made by it to other oversight agencies (such as DSS/DOH) are not within the jurisdiction of HIPAA. In this regard, State law, which continues to protect the confidentiality of information so disclosed, prevails. 3. With regard to complaints filed by patients to CQC, in many cases the patient will have authorized the CQC to have access to his/her PHI in order to investigate the complaint. Hence, such disclosures will have been specifically authorized by the patient. 4. In cases where CQC has exercised its subpoena authority, and/or a court order compelling disclosure has been obtained, covered entities are permitted under HIPAA to disclose PHI under the "required by law" exception.

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>confidential by the commission and by non-profit organizations receiving contracts pursuant to subdivision (k) of section 45.07 of this article and any limitations on the release thereof imposed by law upon the party furnishing the information, books, records or data shall apply to the commission and such non-profit organizations receiving contracts pursuant to subdivision (k) of this article.</p> <p>(b) Pursuant to the authorization of the commission to administer the protection and advocacy system as provided for by federal law, any agency or person within or under contract with the commission, which provides protection and advocacy services, must be granted access at any and all times to any residential facility, or part thereof, serving a person with a mental disability operated, or licensed by any office or agency of the state, and to all books, records and data pertaining to any such facility upon receipt of a complaint by or on behalf of a person with a mental disability. Information, books, records or data which are confidential as provided by law shall be kept confidential by the person or agency within the protection and advocacy system and any limitations on the release thereof imposed by law upon the party furnishing the information, books, records or data shall apply to the person or agency within the protection and advocacy system.</p> <p>(c) In the exercise of its functions, powers and duties, the commission and any member is authorized to issue and enforce a subpoena and a subpoena duces tecum, conduct hearings, administer oaths and examine persons under oath in accordance with and pursuant to civil practice law and rules.</p> <p>(d) In any case where a person in charge or control of such facility or an officer of employee thereof shall fail to comply with the provisions of subdivision (a), the commission may apply to the supreme court for an order directed to such person requiring compliance therewith.</p>		

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>Upon such application the court may issue such order as may be just and a failure to comply with the order of the court shall be a contempt of court and punishable as such.</p>		
<p>MHL §45.17: Functions, powers, and duties of the (Mental hygiene medical review) board: The mental hygiene medical review board shall have the following functions, powers and duties: (a) make a preliminary determination whether the death of a patient or resident in a mental hygiene facility which has been brought to its attention is unusual or whether such death reasonably appears to have resulted from other than natural causes and warrants investigation; (b) investigate the causes of and circumstances surrounding such unusual death or deaths from other than natural causes of patients or residents in mental hygiene facilities (c) visit and inspect any facility in which such a death has occurred; (d) cause the body of the deceased to undergo such examinations including autopsy as in the opinion of the board are necessary to determine the cause of death, irrespective of whether such examination or autopsy shall have been previously performed; and (e) upon review of the cause of and circumstances surrounding the death of any patient or resident, submit its report thereon to the commission and, where appropriate, make recommendations to prevent the recurrence of same to the commissioner of mental hygiene and to the director of the facility.</p>	<p>§164.501: <i>Health oversight agency</i> means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p>§164.512(d): PHI can be released to health oversight agencies for oversight activities authorized by law, including administrative investigations.</p>	<p><u>No preemption:</u> Because the Medical Advisory Review Board is established within and is part of the CQC and, as such, serves in a health oversight agency capacity, covered entities are permitted to release PHI to such Board under the “health oversight agency” exception to HIPAA.</p>
<p>MHL ARTICLES 80, 81:</p> <p>MHL Article 80: Surrogate Decision-Making for Medical Care and Treatment</p> <p>MHL Article 81: Proceedings for Appointment of a Guardian for Personal Needs or Property Management</p>	<p>§164.501: <i>Required by law:</i> a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov’tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government</p>	<p><u>No preemption:</u> In cases where covered entities are asked to disclose PHI in the course and context of a surrogate decision-making or guardianship petition, it is probable that these disclosures will be permitted under the “judicial/administrative proceeding” or “required by law”</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order.</p>	<p>exceptions to HIPAA.</p>
OTHER:		
<p>Notice of Privacy Practices</p> <p>No comparable provision in NYS Mental Hygiene Law</p>	<p>§164.520 Notice of privacy practices for PHI</p> <ol style="list-style-type: none"> 1. An individual has a right to adequate notice of the uses and disclosures of PHI that may be made by the covered entity, and the individual's rights and the covered entity's legal duties with respect to PHI. 2. The notice must contain the following statement as a header or otherwise prominently displayed: THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY. 3. The notice must be written in plain language and contain: (1) a description, including at least 1 example, of the types of uses/disclosures that the covered entity is permitted to make for treatment, payment & health care operations purposes; (2) a description of each of the other purposes for which the covered entity is permitted/required to use/disclose PHI w/out the person's consent/authorization; (3) if a use/disclosure is prohibited or materially limited by other applicable law, the description of such use/disclosure must reflect the more stringent; (4) for each purpose described the description must include sufficient detail to place the person on notice of the uses/disclosures that are permitted/required by HIPAA and other applicable law; (5) a statement that other uses/disclosures will be made only with the person's written authorization and that the individual may revoke such authorization. 4. If the covered entity intends to engage in any of the following, the description must include a separate statement, as applicable, that (1) the covered entity may contact the individual to provide appointment reminders; (2) the covered entity may contact the individual to raise funds; (3) a group health plan..may disclose PHI to the sponsor. 5. The notice must contain a statement of the individual's rights with respect to PHI and a brief description of how the person can exercise those rights (i.e., right to request restrictions, right to receive confidential communications, right to inspect/copy PHI, right to amend PHI, right to receive accounting of disclosures, 	<p>The Federal rule applies as there is no comparable provision of law in the NYS Mental Hygiene Law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>and right to receive paper copy of the notice, if notice is received electronically).</p> <p>6. The notice must contain covered entity requirements (i.e, statement that the covered entity is required by law to maintain the privacy of PHI and to provide the notice of its legal duties and privacy practices; a statement that the covered entity is required to abide by the terms of the notice; in order for the covered entity to apply a change in its privacy practices, a statement that it reserves the right to change the terms of its notice and to make the new notice provision effective for all PHI it maintains (must also describe how it will provide persons with a new notice).</p> <p>7. Complaints. The notice must contain a statement that individuals may complain to the covered entity and the Secretary of HHS if they believe their privacy rights have been violated; a brief description of how to file a complaint with the covered entity; and advise of nonretaliation for filing a complaint.</p> <p>8. Contact. The notice must contain a contact name, or title, and telephone # of a person/office to contact for further information.</p> <p>9. Effective date. The notice must contain the date on which the notice is first in effect, which cannot be earlier than the date on which it is printed/published.</p> <p>10. Provisions for optional contents are also included.</p> <p>11. A covered health care provider with a direct treatment relationship with the patient must provide the notice no later than the date of first service delivery, and, except in an emergency situation, make a good faith effort to obtain a written acknowledgment.</p> <p>12. Whenever the notice is revised, the notice must be made available upon request on or after the effective date of the revision and promptly comply with the acknowledgment requirements.</p> <p>13. Electronic notice is permitted.</p>	
<p>Right to request Restrictions</p> <p>No comparable provision in NYS Mental Hygiene Law</p>	<p>§164.522 (a)(1) Right to request restrictions. A covered entity must permit an individual to request that the covered entity restrict (1) uses/disclosures of PHI about the individual to carry out treatment, payment and health care operations and (2) disclosures of PHI for involvement in the individual's care and notification purposes. A covered entity does not have to agree to these restrictions.</p>	<p>The Federal rule applies as there is no comparable provision of law in the NYS Mental Hygiene Law, provided, however, that although MHL does not list this out as an express right, the opportunity to restrict disclosures of PHI for care and notification purposes exists as a standard practice in the New York State public mental health system and is indirectly addressed MHL §33.13.</p>
<p>Right to request Accountings</p> <p>No comparable provision in NYS Mental Hygiene Law</p>	<p>§164.528 (a)(1) Right to request accountings. An individual has a right to receive an accounting of disclosures of PHI made by a covered entity in the 6 years prior to the date on which an accounting is requested, except for disclosures: (1) to carry out treatment, payment, and health care operations; (2) to the individuals themselves; (3) that are made for national security or intelligence</p>	<p>The Federal rule applies as there is no comparable provision of law in the NYS Mental Hygiene Law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>purposes; (4) that are related to certain custodial situations; (5) to correctional institutions and law enforcement officials; and (6) which occurred prior to the compliance date for the covered entity.</p> <p>§164.528 (c): The covered entity must act on the individual's request for an accounting no later than 60 days after receipt of such request by providing the accounting or requesting an extension of no more than 30 days. The first accounting must be provided without charge, and thereafter a reasonable, cost-based fee for each subsequent accounting may be charged if the individual is informed in advance of the fee and an opportunity to modify the request to reduce or avoid the fee.</p> <p>§164.528 (d): Documentation. A covered entity must retain documentation of the information required to be included in an accounting, the written accounting provided to the individual, and titles of persons or responsible officers who process/receive accountings.</p>	
<p>Administrative Requirements:</p> <p>No comparable provisions in NYS Mental Hygiene Law</p>	<p>§164.530 (a)(1): Personnel Designations: A covered entity must designate a privacy official who is responsible for the development and implementation of the policies/procedures of the entity.</p> <p>§164.530 (a)(2) Documentation: A covered entity must document the required personnel designations.</p> <p>§164.530 (a)(3) Training: A covered entity must train all members of its workforce on the policies/procedures with respect to PHI required by HIPAA, as necessary and appropriate to carry out their functions within the covered entity. The workforce must be trained prior to the compliance date; new members must be trained within a reasonable time after joining the workforce..... Such training must be documented.</p> <p>§164.530 (c) Safeguards. A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI...</p> <p>§164.530 (d)(1): Complaints. A covered entity must provide a process for individuals to make complaints concerning: (1) the covered entity's policies and procedures required by HIPAA and (2) its compliance with such policies and procedures or the requirements of HIPAA.</p> <p>§164.530 (d)(2) Documentation of complaints: A covered entity must document all complaints received, as well as their disposition.</p> <p>§164.530 (e)(1),(2) Sanctions: A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with HIPAA... Those</p>	<p>The Federal rule applies as there is no comparable provision of law in the NYS Mental Hygiene Law.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>sanctions must be documented.</p> <p>§164.530 (f): Mitigation: A covered entity must mitigate, to the extent practicable, any harmful effects known to the covered entity of a use/disclosure of PHI in violation of its policies/procedures or HIPAA by the covered entity or its business associate.</p> <p>§164.530 (g) Retaliatory acts: A covered entity may not intimidate, threaten, coerce, discriminate against, or take retaliatory action against any individual for exercising his/her rights or for filing a complaint with HHS...</p> <p>§164.530 (h): Waiver: A covered entity may not require individuals to waive their rights to file complaints or any other rights under HIPAA as a condition of provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.</p> <p>§164.530 (i)(1),(2),(3),(4) Policies and procedures: A covered entity must implement policies and procedures with respect to PHI designed to comply with the requirements of HIPAA.... Such policies/procedures must be changed as necessary to comply with changes in the law ..must document and implement the revised policies/procedures promptly....and must revise its Notice of Privacy Practices.</p> <p>§164.530 (j)(1),(2) Retention of policies: A covered entity must maintain the required policies/procedures in written or electronic form, copies of communications HIPAA requires, and records of any action, activity, or designation HIPAA requires to be documented. Such documentation must be retained for 6 years from date of creation or date last in effect, whichever is later.</p>	
CRIMINAL PROCEDURE LAW		
<p>CPL §330.20 Procedure following verdict or plea of not responsible by reason of mental disease or defect</p> <p>2. Examination order; psychiatric examiners. Upon entry of a verdict of not responsible by reason of mental disease or defect, or upon the acceptance of a plea of not responsible by reason of mental disease or defect, the court must immediately issue an examination order. Upon receipt of such order, the commissioner must designate 2 qualified psychiatric examiners to conduct the examination to</p>	<p>§164.501: <i>Required by law:</i> a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.501: <i>Correctional institution</i> means any penal or correctional facility....for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other person held in lawful custody. Other persons held in lawful</p>	<p><u>No Preemption:</u> HIPAA and State law are consistent; State law applies.</p> <p>1. The disclosures of information by the commissioner to qualified psychiatrists, and by the qualified psychiatrists to the commissioner of OMH/OMRDD and court, and by the commissioner to the court, are permitted by HIPAA because they are required by law and are necessary in the course of a judicial proceeding.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>examine the defendant. In conducting their examination, the psychiatric examiners may employ any method which is accepted by the medical profession for the examination of persons alleged to be suffering from a dangerous mental disorder or to be mentally ill or retarded. The court may authorize a psychiatrist or psychologist retained by the defendant to be present at such examination. The clerk of the court must promptly forward a copy of such examination order to the mental hygiene legal service and such service may thereafter participate in all subsequent proceedings under this section.</p> <p>5. Examination order; reports. After he has completed his examination of the defendant, each psychiatric examiner must promptly prepare a report of his findings and evaluation concerning the defendant's mental condition and submits such report to the commissioner. If the psychiatric examiners differ in their opinion as to whether the defendant is mentally ill/is suffering from a dangerous mental disorder, the commissioner must designate another psychiatric examiner to examine the defendant. Upon receipt of the examination reports, the commissioner must submit them to the court that issued the examination order. If the court is not satisfied with the findings of these psychiatric examiners, the court may designate one or more additional psychiatric examiners pursuant to subdivision fifteen of this section. The court must furnish a copy of the reports to the district attorney, counsel for the defendant, and the mental hygiene legal service.</p> <p>6. Initial hearing, commitment order. ...If the court finds that the defendant has a dangerous mental disorder, it must issue a commitment order.</p> <p>8. First retention order. When a defendant is in the custody of the commissioner pursuant to a commitment order..... <i>continued, next row)</i></p>	<p>custody includes...persons committed to mental institutions through the criminal justice system.</p> <p>§160.501:Law enforcement official means an officer or employee of any agency or authority, of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) investigate or conduct an official inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814)</p> <p>§164.512(j):A covered entity may use/disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the information cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment. disclosures are about an inmate and are necessary for the health and safety of the inmate and others, and because they are being made to law enforcement officials to avert a threat to public health and safety.</p> <p>§164.512(k)(5) Correctional institutions and other law enforcement custodial situations.(i) A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual PHI about such inmate or individual, if the correctional institution or such law enforcement official represents that such PHI is necessary for: (A) the provision of health care to such individuals; (B) the health and safety of such individual/other inmates; (C) the health/safety of the officers or employees of or others at the correctional institution; (D) the health/safety of such individuals/officers/other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another; (E) law enforcement on the premises of the</p>	<p>2. All disclosures in this section of law made by the court to MHLS are not impacted by HIPAA, since the court is not a covered entity under HIPAA.</p> <p>3. Disclosures by a covered entity (OMH/OMRDD) to the district attorney and to the counsel for the defendant in the context of (as applicable) applications for first retention orders, second & subsequent retention orders, discharge orders, and recommitment orders, are all permitted by HIPAA as they are required by law and/or are necessary disclosures in the course of a judicial proceeding.</p> <p>4. Disclosures made by a covered entity (OMH/OMRDD) prior to the discharge or release of a person committed to the custody of the commissioner pursuant to a criminal court order are permitted under HIPAA because they are required by law.</p> <p>5. Disclosures made by a covered entity (OMH/OMRDD) pursuant to the escape of a person committed to the custody of the commissioner pursuant to a criminal court order are permitted under HIPAA because they are required by law, because the disclosures are about an inmate and are necessary for the health and safety of the inmate and others, and because they are being made to avert a threat to public health and safety.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>The commissioner must give written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>9. Second and subsequent retention orders. When a defendant is in the custody of the commissioner pursuant to a first retention order..... The commissioner must give written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>10. Furlough order. The commissioner may apply for a furlough order....The commissioner must give ... written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>11. Transfer order. The commissioner may apply for a transfer order....The commissioner must give ... written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>12. Release order and order of conditions. The commissioner may apply for a release order....The commissioner must give ... written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>13. Discharge order. The commissioner may apply for a discharge order....The commissioner must give ... written notice of the application to the district attorney , the defendant, counsel for the defendant, and the mental hygiene legal service...</p> <p>14. Recommitment order. At any time.. an application may be made by the commissioner or the district attorney for a recommitment order....The applicant must give written notice of the application to the defendant, counsel for the defendant, and the mental hygiene legal service and if the applicant is the commissioner he must give such notice to the district attorney and if the applicant is the district attorney he</p>	<p>correctional institution; and (F) the administration and maintenance of the safety, security & good order of the correctional institution.</p>	

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>must give such notice to the commissioner....</p> <p>15. Designation of psychiatric examiners. ...If at any hearing.....the court may direct the commissioner to designate one or more psychiatric examiners to conduct an examination of the defendant and submit a report of their findings. In addition, the court may...designate one or more psychiatric examiners to examine the defendant and submit a report of their findings.</p> <p>18. Notwithstanding any other provision of law, no person confined by reason of commitment order, recommitment order or retention order to a secure facility may be discharged/released unless the commissioner shall deliver written notice...in advance of such discharge/release to all of the following: (a) the district attorney; (b) the police department having jurisdiction of the area to which the defendant is to be discharged or released; (c) any other person the court may designate.</p> <p>19. Escape from custody, notice requirements. If a defendant is in the custody of the commissioner pursuant to an order issued under this section, and the defendant escapes from custody, immediate notice of such escape shall be given to: (a) the district attorney; (b) the superintendent of state police; (c) the sheriff of the county where the escape occurred; (d) the police department having jurisdiction of the area where the escape occurred; (e) any person the facility staff believes to be in danger; and (f) any law enforcement agency and any person the facility staff believes would be able to apprise such endangered person that the defendant has escaped from the facility...</p> <p>(Also see OMH Official Policy Manual QA-520)</p>		
<p>CPL §730.20 Fitness to proceed; generally.</p> <p>1. The appropriate director (of a state</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law;</p>	<p><u>No Preemption:</u> HIPAA and State law are consistent; State law applies.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>OMH/OMRDD hospital) to whom a criminal court issues an order of examination must be determined....Upon receipt of the examination order, the director may designate 2 qualified psychiatric examiners, of whom he may be one, to examine the defendant to determine if he is an incapacitated person. In conducting their examination, the psychiatric examiners may employ any method which is accepted by the medical profession for the examination of persons alleged to be mentally ill or mentally defective. The court may authorize a psychiatrist or psychologist retained by the defendant to be present at such examination.</p> <p>5. Each psychiatric examiner, after he has completed his examination of the defendant, must promptly prepare an examination report and submit it to the director...Upon receipt of the examination reports, the director must submit them to the court that issued the order of examination. The court must furnish a copy of the reports to counsel for the defendant and to the district attorney.</p>	<p>includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814:</p>	<p>1. The disclosures of information by the director to qualified psychiatrists, and then by qualified psychiatrists back to the director and court, are permitted by HIPAA because they are required by law and are necessary in the course of a judicial proceeding.</p> <p>2. Disclosures to the court by the director are permitted by HIPAA as they are required by law and/or are necessary disclosures in the course of a judicial proceeding.</p>
<p>CPL §730.40 Fitness to proceed; local criminal court accusatory instrument.</p> <p>4.....If the director has submitted the examination reports to the local criminal court, such court must forward them to the superior court in which the indictment was filed. If the director has not submitted such reports to the local criminal court, he must submit them to the superior court in which the indictment was filed.</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful</p>	<p><u>No Preemption:</u> HIPAA and State law are consistent; State law applies.</p> <p>1. Disclosures of information by the local criminal court to the superior court are not impacted by HIPAA as neither are covered entities.</p> <p>2. Disclosures to the court by the director are permitted by HIPAA as they are required by law and/or are necessary disclosures in the course of a judicial proceeding.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814)	
<p>CPL §730.50 Fitness to proceed; indictment.</p> <p>2. When a defendant is in the custody of the commissioner (of OMH/OMRDD) immediately prior to the expiration of the period prescribed in a temporary order of commitment and the superintendent of the institution wherein the defendant is confined is of the opinion that the defendant continues to be an incapacitated person, such superintendent must apply to the court that issued the order for an order of retention....The superintendent must give written notice of the application to the defendant and to the mental hygiene legal service. ...</p> <p>4. When a defendant is in the custody of the commissioner at the expiration of the authorized period prescribed in the last order of retention....and the commissioner must promptly certify to such court and to the appropriate district attorney that the defendant was in his custody on such expiration date...</p> <p>5. When...any defendant remains in the custody of the commissioner pursuant to an order.....the superintendent or director of the institution where the defendant is confined shall, if he believes that the defendant continues to be an incapacitated person, apply forthwith to a court....for an order of retention.</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814)</p>	<p><u>No Preemption:</u> Disclosures to the court by the commissioner are permitted by HIPAA as they are required by law and/or are necessary disclosures in the course of a judicial proceeding. HIPAA and State law are consistent; State law applies</p>
<p>CPL §730.60 Fitness to proceed; procedure following custody by commissioner. 1. When a local criminal court issues a final or temporary order of observation or order of commitment.....Upon receipt thereof, the commissioner must designate an appropriate institution operated by the department of mental hygiene in which the defendant is to be</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government</p>	<p><u>No Preemption:</u> HIPAA and State law are consistent; State law applies.</p> <p>1. The disclosures of information by the superintendent to the court are permitted by HIPAA because they are required by law and are necessary in the course of a judicial proceeding.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
<p>placed.</p> <p>2. Except as otherwise provided....such order is suspended until the superintendent of the institution in which the defendant is confined determines that he is no longer an incapacitated person. In that event, the court that issued such order and the appropriate district attorney must be notified, in writing, by the superintendent of his determination....</p> <p>6. (a) Notwithstanding any other provision of law, no person committed to the custody of the commissioner pursuant to this article, or continuously retained thereafter in such custody, may be discharged/released on condition or placed in any less secure facility or on any less restrictive status, including but not limited to vacations, furloughs, or temporary passes, until the the commissioner shall deliver written notice...in advance of the change to all of the following: (a) the district attorney of the county from which such person was committed; (b) the superintendent of state police, (c) the sheriff of the county where the facility is located; (d) the police department having jurisdiction of the area where the facility is located; (e) any person who may reasonably be expected to be the victim of any assault or any violent felony offense...; and (f) any other person the court may designate....</p> <p>(b) The notice ...shall also be given immediately upon the departure of such committed person from the commissioner's actual custody, without proper authorization...</p>	<p>program providing public benefits.</p> <p>§164.501: Correctional institution means any penal or correctional facility....for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other person held in lawful custody. Other persons held in lawful custody includes...persons committed to mental institutions through the criminal justice system.</p> <p>§160.501:Law enforcement official means an officer or employee of any agency or authority, of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) investigate or conduct an official inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(e): PHI can be released w/out patient consent in the course of any judicial or administrative proceeding(1)in response to an order of a court or administrative tribunal, provided release is limited to that PHI expressly authorized in the order; or(2) in response to a subpoena, discovery request, or other lawful process if the covered entity has made reasonable efforts to give the patient notice of the request or the covered entity is assured that reasonable efforts have been made to secure a qualified protective order. (p.82814:</p> <p>§164.512(j):A covered entity may use/disclose PHI (consistent with law & professional conduct) if it believes in good faith that the disclosure is necessary to prevent or lessen a serious & imminent threat to the health or safety of a person (per preamble, consistent with Tarasoff) or the public and is being made to a person or persons reasonably able to prevent or lessen the threat or is necessary for law enforcement authorities to identify/apprehend an individual. If disclosure is to be made to one other than the target, the information cannot have been obtained in the course of treatment to affect the propensity to commit the criminal conduct or through a request by the person to initiate or be referred to treatment.</p> <p>§164.512(k)(5) Correctional institutions and other law enforcement custodial situations.(i) A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual PHI about such inmate or individual, if the correctional institution or such law enforcement official represents that such PHI is necessary for: (A) the provision of health care to such individuals; (B) the health and safety of such individual/other inmates; (C) the health/safety of the officers or employees of or others at the correctional institution; (D) the health/safety of such individuals/officers/other persons responsible for the transporting of inmates or their transfer form one institution, facility, or setting to another; (E) law enforcement on the premises of the correctional institution; and (F) the administration and maintenance of the safety, security & good order of the correctional institution.</p>	<p>2. Disclosures by a covered entity (OMH/OMRDD) to the district attorney are permitted by HIPAA as they are required by law and/or are necessary disclosures in the course of a judicial proceeding.</p> <p>3. Disclosures made by a covered entity (OMH/OMRDD) prior to the discharge or release of a person committed to the custody of the commissioner pursuant to a criminal court order are permitted under HIPAA because they are required by law, because the disclosures are about an inmate and are necessary for the health and safety of the inmate and others, and because they are being made to law enforcement officials to avert a threat to public health and safety.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
CIVIL PRACTICE LAW AND RULES SECTION 2302: Subpoenas		
<p>CPLR 2302 (a): Subpoenas may be issued without a court order by the clerk of the court, a judge where there is no clerk, the attorney general, an attorney of record for a party to an action, an administrative proceeding or an arbitrator.....provided, however, that a subpoena to compel production of a patient's clinical record maintained pursuant to the provisions of section 33.13 of the MHL shall be accompanied by a court order...</p>	<p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p>	<p><u>No preemption</u> State law applies, since it is more stringent by preventing disclosure without an accompanying court order, which can only be made after specific findings have been made.</p>
PENAL LAW SECTION 400: Firearms		
<p>Penal Law §400(4) Investigation. Before a license(to possess or deal in firearms) is issued or renewed, there shall be an investigation of all statements required in the application by the duly constituted police authorities of the locality where such application is made. For that purpose, the records of the appropriate office of the department of mental hygiene concerning previous or present mental illness of the applicant shall be available for inspection by the investigating officer of the police authority....Upon completion of the investigation, the police authority shall report the results to the licensing officer without unnecessary delay.</p>	<p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(f) Disclosures for law enforcement purposes. A covered entity may</p>	<p><u>No Preemption:</u> Because of the nexus between the need for the disclosure by law enforcement and public safety, State law and the HIPAA Privacy regulation are consistent and State law applies. Additionally, though not legally necessary, it is possible that through the application process the individual is authorizing this disclosure.</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	<p>disclose PHI: (i) as required by law including laws that require the reporting of certain types of wounds...(ii) In compliance with and as limited by the relevant requirements of...(C) an administrative request..., provided that: (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) De-identified information could not reasonably be used.</p> <p><i>Preamble:</i> "The importance and legitimacy of law enforcement activities are beyond question, and they are not at issue in this regulation. We permit disclosure of protected health information to law enforcement officials without authorization in some situations precisely because of the importance of these activities to public safety." (P. 82678:3)</p>	
LABOR LAW SECTIONS 458,459: Explosives		
<p>Labor Law §458(5): Before a license or certificate (to deal in explosives) is issued, the Commissioner of Labor shall have the authority to request and receive from any department, division, board, bureau, commission or agency of the state or local government thereof such assistance and information as will enable him properly and effectively to carry out his powers and duties under this article.</p> <p>Labor Law §459 (1): A license or certificate (to deal in explosives) may be denied where the Commissioner of Labor has probably reason to believe...after due investigation...that the applicant...has been confined as a patient or inmate in a public or private institution for the treatment of mental diseases...</p>	<p>§164.501: Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.</p> <p>§164.512(f) Disclosures for law enforcement purposes. A covered entity may disclose PHI: (i) as required by law including laws that require the reporting of certain types of wounds...(ii) In compliance with and as limited by the relevant requirements of...(C) an administrative request..., provided that: (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) De-identified information could not reasonably be used.</p> <p><i>Preamble:</i> "The importance and legitimacy of law enforcement activities are beyond question, and they are not at issue in this regulation. We permit disclosure of protected health information to law enforcement officials without authorization in</p>	<p>No Preemption: Because of the nexus between the need for the disclosure by law enforcement and public safety, State law and the HIPAA Privacy regulation are consistent and State law applies. Additionally, though not legally necessary, it is possible that through the application process the individual is authorizing this disclosure</p>

NYS Statute	HIPAA Regulation (45 CFR Parts 160, 164)	Preemption Analysis
	some situations precisely because of the importance of these activities to public safety." (P. 82678:3)	
Federal Law	HIPAA Regulation	Compatability Analysis
<p>FEDERAL PROTECTION AND ADVOCACY FOR THE MENTALLY ILL:</p> <p>42 USCA §10806: An eligible system which has access to records which, under federal or State law, are required to be maintained in a confidential manner by a provider of health services shall, except as provided in subsection (b) of this section, maintain the confidentiality such records to the same extent as is required of the provider of services.</p> <p>A system established in a State under section 10803 of this title to protect and advocate the rights of individuals with mental illness shall....(4) in accordance with section 10806 of this title, have access to all records of...(A) any individual who is a client of the system if such individual, or the legal guardian, conservator, or other legal representative of such individual, has authorized the system to have such access; (B) any individual(including an individual whose whereabouts are unknown) (i) who, by reason of the mental or physical condition of such individual is unable to authorize the system to have such access; (ii) who does not have a legal guardian, conservator, or other legal representative, or for whom the legal guardian is the State; and (iii) with respect to whom a complaint has been received by the system or with respect to whom as a result of monitoring or other activities...there is probable cause to believe that such individual has been subject to abuse or neglect; and (C) any individual with a mental illness, who has a legal guardian, conservator, or other legal representative, with respect to whom a complaint has been received by the</p>	<p>§164.502(a)(1): A covered entity is permitted to use/disclose PHI to the patient (including a patient's personal representative, i.e., someone authorized to act on patient's behalf to make health care decisions).</p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid under this section. (p. 82811:1)</p> <p>§164.512(c)(1): Disclosures about victims of abuse, neglect, or domestic violence. Except for reports of child abuse or neglect....a covered entity may disclose PHI about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence: (i) to the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law; (ii) if the individual agrees to the disclosure; or (iii) to the extent the disclosure is expressly authorized by statute or regulation and: (A) the covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims or (B) if the individual is unable to agree because of incapacity, a law enforcement official or other public official authorized to receive the report represents that the PHI for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure. <i>(continued, next row)</i></p> <p>§164.512(c)(2) Informing the individual. A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been/will be made, except if: (i) the covered entity, in the exercise of professional judgment, believes informing the individual would place him/her at serious risk of harm; or (ii) the covered entity would be informing a personal representative and the covered entity reasonably believes he/she is the perpetrator and informing him/her would not be in the patient's best interests, using professional judgment</p>	<p>The two sets of federal regulations appear similar, in that disclosures to PAMI systems are not permitted unless the patient has authorized the disclosure, or in instances involving abuse that are accommodated in HIPAA; however, HIPAA should be followed to ensure requisite attempts to notify the individual are made.</p>

Federal Law	HIPAA Regulation	Compatability Analysis
<p>system or with respect to whom there is probable cause to believe the health or safety of the individual is in serious and immediate jeopardy, whenever (i) such representative has been contacted by such system upon receipt of the name and address of the representative; (ii) such system has offered assistance to such representative to resolve the situation; and (iii) such representative has failed or refused to act on behalf of the individual.</p>	<p>§164.512(j): A covered entity may, consistent with applicable law and standards of ethical conduct, use/disclose PHI if it believes, in good faith, that the use/disclosure (i)(A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) is to a person(s) reasonably able to prevent/lessen the threat.</p>	
<p>42 CFR PART 2: Confidentiality of Alcohol and Drug Abuse Patient Records</p>		
<p>§2.4 Criminal penalty for violation. Under 42 USC 290ee-3(f) and 42 USC 290-dd3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.</p>	<p>§160.312(a)(2): If a covered entity fails to adhere to the privacy regulations, it is subject to civil/criminal penalties initiated by HHS. Non-compliant entities are subject to civil monetary penalties ranging from \$100 to \$25,000, depending on the extent of non-compliance. Misdemeanor or felony criminal penalties apply if a covered entity wrongfully/knowingly discloses PHI in violation of HIPAA. Criminal violations are punishable by fines up to \$250,000 or imprisonment (a maximum of 10 years) or both.</p>	<p>HIPAA penalties are more severe than those under 42 CFR Part 2; it is unclear which penalties would apply to a program covered by both in the event of an unauthorized use/disclosure of PHI, but may be fact dependent.</p>
<p>§2.11 Definitions</p> <p><i>Diagnosis:</i> means any reference to an individual's alcohol/drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral to treatment.</p> <p><i>Patient identifying information:</i> means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p> <p>§160.103: Health Information means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p> <p>§160.103: Individually identifiable health information: is information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.</p> <p>§160.103: Protected health information: is individually identifiable health</p>	<p>1. HIPAA broadly applies to "covered entities;" 42 CFR Part 2 applies to "federally assisted alcohol/drug program." Hence, unless a covered entity is also a federally assisted alcohol/drug program, it is not bound by 42 CFR Part 2. A federally assisted alcohol/drug program that is also a covered entity is bound both by HIPAA and 42 CFR Part 2.</p> <p>2. The HIPAA definition of "protected health information" covers a wider scope of information than does 42 CFR Part 2. Hence, the HIPAA definition of PHI preempts the definition of "patient identifying information" in 42 CFR Part 2.</p>

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<p><i>Record</i> means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.</p> <p><i>Federally assisted</i> : means an alcohol drug program that (1) receives federal funds in any form, even if the funds do not directly pay for the alcohol/drug services; or (2) is assisted by the IRS through grant of tax exempt status or allowance of tax deductions for contributions; or (3) is authorized to conduct business by the federal government; or (4) is conducted directly by the federal government.</p>	<p>information that is transmitted or maintained in any medium.</p> <p>§164.514(b): Requirements for de-identification of PHI: (2)(i): [Information is considered de-identifying if] ...the following identifiers are removed: (A) Names; (B) all geographic subdivisions smaller than a State...; (C)all elements of dates, except year for dates directly related to an individual...;(D) telephone #s; (E)fax #s; (F) e-mail addresses; (G) SS#s; (H) medical record #s; (I) health plan beneficiary #s; (J) account #s; (K) certificate/license #s; (L)vehicle identifiers and serial #s...; (M)device identifiers and serial #s; (N)URLs; (O) IP address #s; (P)biometric identifiers; (Q) full face photographic images and any comparable images; and (R) any other unique identifying #, characteristic or code; and (ii) the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.</p>	
<p>§2.11 Definitions</p> <p>Patient means any individual who has applied for or been given diagnosis or treatment for alcohol/drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol/drug abuser in order to determine that person's eligibility to participate in a program.</p>	<p>§164.501: Individual means the person who is the subject of protected health information.</p> <p>§164.502(g):A "personal representative" can fulfill the role of the individual about whom PHI pertains if the representative has authority to act on behalf of the individual in making decisions about health care.</p>	<p>1. The definitions of "patient" and "individual" are similar; although in some respects the 42 CFR Part 2 definition is more broad; therefore, a provider covered by both should follow the 42 CFR Part 2 definition.</p> <p>2. Both regulations permit "personal representatives" to stand in the patient's shoes with regard to consenting for the use/disclosure of health information. However, the HIPAA definition is more narrow in that it defines a "personal representatives" as a person who has authority to act on behalf of the individual in making decisions about health care. 42 CFR Part 2 would permit a person with power of attorney over fiscal affairs (i.e., he/she is authorized under law to act in the patient's behalf, albeit in limited regard) to provide such consent. Therefore, the HIPAA definition of</p>

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		<p>"personal representative" is more stringent than 42 CFR Part 2 and controls.</p>
<p>§2.11 Definitions Qualified Service organization: means a person which: (a) provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting 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 (b) Has entered into a written agreement with a program under which that person: (1) acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by 42 CFR Part 2; and (2) if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as provided by 42 CFR Part 2.</p> <p>§2.12(c)(4): The restrictions on disclosure in these regulations do not apply to communications between a program and a QSOA of information needed by the organization to provide services to the program.</p>	<p>§160.103 Business Associate means a person or entity other than a member of the covered entity's workforce that performs or assists in performing a function or activity on behalf of the covered entity that involves the use or disclosure of PHI.</p> <p>§164.504: Uses & disclosures; organizational requirements (e)(1): Business associate contracts: Business associate contracts must: (1) establish the BA's permitted and required uses and disclosures of PHI; (2) prohibit the BA from using/further disclosing PHI, except as permitted by HIPAA; (3) BA must use appropriate safeguards to prevent unauthorized use/disclosure of the information; (4) BA must report to the covered entity if it becomes aware of any use/disclosure of PHI in violation of the contract; (5) BA must ensure that its agents/subcontractors agree to the same restrictions on use/disclosure of PHI; (6) BA must make PHI available for amendment and incorporate any amendments to PHI; (7) BA's internal practices, books, and records relating to use/disclosure of PHI must be made to the HHS for purposes of determining compliance; (8) at termination of the contract: (a) if feasible, return or destroy all PHI the BA maintains in any form and retain no such copies of such information; (b) or, if return/destruction is not feasible, continue the protections of the contract to the PHI and limit further uses/disclosures to the purposes that make return or destruction of the PHI infeasible; (9) the contract must allow the covered entity to terminate the contract if the covered entity determines that the BA has violated a material term.</p> <p><i>Preamble:</i> A covered entity may disclose PHI to a business associate, consistent with the other requirements of the final rule, as necessary to permit the business associate to perform functions and activities for or on behalf of the covered entity.a business associate may only use the PHI it receives in its capacity as a business associate to a covered entity as permitted by its contract or agreement with the covered entity. (p. 82504:2)</p>	<p>1. A "qualified services organization" is a subset of a "business associate;" the HIPAA term "business associate" is more broad than is QSOA. Therefore, programs covered by both HIPAA and 42 CFR Part 2 should follow the definition of "business associate" in making determinations as to entities with which it needs to have formalized agreements.</p> <p>2. Business Associate agreements under HIPAA have 9 required elements, while QSOAs under 42 CFR Part 2 have only 2. Therefore, programs covered by both will need to ensure all 11 elements are addressed in their formalized agreements.</p> <p>3. If an entity covered by both HIPAA and 42 CFR has a QSOA relationship, but PHI is not necessarily needed in order to perform that service (which is not a requirement for something to be considered a QSOA) it would not constitute a "business associate" relationship for purposes of HIPAA. Hence, disclosures would not be permitted without patient authorization. In this regard, HIPAA is more stringent than 42 CFR Part 2 and prevails.</p>
<p>§2.12(c)(1) Applicability: Veterans Administration: These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38</p>	<p>§160.103: Health Information means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p>	<p>Further analysis is required to determine whether or not the provisions of 38 U.S.C. 4132 and corresponding regulations are equally, or more, stringent than HIPAA. If they are, this provision of 42 CFR Part 2 cannot be followed. If they are not, however, this provision of 42 CFR Part 2 will, in fact,</p>

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U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans Affairs.		prevail.
<p>§2.12(c)(2) Applicability: Exceptions Armed Forces: These regulations apply to any information 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 Veterans Administration furnishing health care to veterans.</p>	<p>§160.103: Health Information means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p>	<p>HIPAA applies to all health information; to the extent 42 CFR Part 2 “carves out” a subset of health information, depending on where/how it was obtained, to which the regulations do not apply, it provides less protection/access to health records than does HIPAA, and programs covered by both sets of regulations should comply with HIPAA in this regard.</p>
<p>§2.12(c)(3) Applicability: Exceptions Communication within a program or between a program and an entity having direct administrative control over that program. The restrictions on disclosure in these regulations 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 alcohol/drug abuse if the communications are (1) within a program; or (2) between a program and an entity that has direct administrative control over the program.</p>	<p>§164.502 (b)(2) Minimum necessary does not apply to: (i) disclosures to or requests by a health care provider for treatment....</p> <p>§164.504 (a) Definitions: <i>Common control</i> exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.</p> <p><i>Common ownership</i> exists if an entity ...possesses an ownership or equity interest of 5% or more in another entity.</p> <p>(d)(1) <i>Affiliated covered entities.</i> Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this subpart. (2)(i) legally separate covered entities may designate themselves ...as a single affiliated covered entity ...if all of the covered entities designated are under common ownership or control.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow 42 CFR Part 2 in regard to intra-program communications; while both rules are similar, 42CFR Part 2 more strictly defines the concept of an affiliated entity.</p>
<p>§2.12(c)(5) Applicability: Crimes on program premises: The restrictions on disclosure and use ...do not apply to communications from program personnel to law enforcement officers which (i) are directly related to a patient’s commission of a crime on the premises of the program or against 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/threatening to commit the crime,</p>	<p>§164.512(f)(5): Crime on program premises. A covered entity may disclose to a law enforcement official PHI that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow 42 CFR Part 2 in regard to reporting crimes on program premises. While the rules are similar, 42CFR Part 2 contains limitations on the amount of information that can be so disclosed.</p>

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that individual's name and address, and that individual's last known whereabouts.		
<p>§2.12(c)(6) Applicability: Exceptions: Reports of suspected child abuse or neglect. The restrictions on disclosure and use in these regulations 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 alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse or neglect.</p>	<p>§164.512(b): A covered entity may disclose PHI for the public health activities and purposes described in this paragraph to: (ii) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow 42 CFR Part 2 in regard to child abuse reporting; while both rules are similar, 42CFR Part 2 reinforces the confidentiality of such records for any purpose beyond the making of the report.</p>
<p>§2.12(d) Applicability: Applicability to recipients of information (1) Restriction on use of information. The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, ...the introduction of that information as evidence in a criminal proceeding and any other use of that information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants..or through patient access..is subject to the restriction on use.</p>	<p>No comparable provision.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow this provision of 42 CFR Part 2.</p>
<p>§2.12(d) Applicability: Applicability to recipients of information (2) Restriction on disclosures - Third party payers, administrative entities, and others. The restrictions on disclosure in these regulations apply to: (1) 3rd party payers with regard to</p>	<p>§160.103: Covered entity means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow this provision of 42 CFR Part 2; it is broader in reach than is HIPAA and would cover all health care providers, regardless of whether or not they engage in</p>

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<p>records disclosed to them by federally assisted alcohol or drug abuse programs; (2) Entities having direct administrative control over programs with regard to information communicated to them by the program under §2.12(c)(3), (3) persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with §2.32 of these regulations.</p>		<p>electronic transactions.</p>
<p>§2.12(e) Explanation of applicability (1) Coverage: These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program, (a defined term) if the program is federally assisted in any manner (a defined term). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and do provide, alcohol/drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol/drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.</p>	<p>§160.103: <i>Health Information</i> means any information, whether oral or recorded in any medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.</p>	<p>HIPAA covers a much wider range of providers and information than does 42 C.F.R. Part 2. Programs covered by both 42 CFR Part 2 and HIPAA should continue to follow this provision of 42 CFR Part 2 for guidance as to what information that is under the jurisdiction of such regulation.</p>
<p>§2.12(e) Explanation of applicability (2) Federal assistance to program required: If a patient's alcohol/drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated, or supported in a manner which constitutes federal</p>	<p>§160.103: <i>Covered entity</i> means: (1) a health plan; (2) a health care clearinghouse; (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</p>	<p>HIPAA covers a much wider range of providers and entities than does 42 C.F.R. Part 2. Programs covered by both 42 CFR Part 2 and HIPAA should continue to follow this provision of 42 CFR Part 2 for guidance as to what providers/entities under the jurisdiction</p>

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assistance.....that patient's record is not covered by this regulation....		of such regulation.
<p>§2.12(e) Explanation of applicability (3) Information to which restrictions are applicable. Whether a restriction is on use/disclosure affects the type of information which may be available (sic). The restrictions on disclosure apply to any information which would identify a patient as an alcohol/drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment or referral for treatment of alcohol/drug abuse.</p>	<p>§160.103: <i>Individually identifiable health information:</i> is information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.</p> <p>§160.103: <i>Protected health information:</i> is individually identifiable health information that is transmitted or maintained in any medium.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow this provision of 42 CFR Part 2</p>
<p>§2.12(e) Explanation of applicability (4) How type of diagnosis affects coverage. These regulations cover any record of a diagnosis identifying a patient as an alcohol/drug abuser which is prepared in connection with the treatment/referral for treatment of alcohol/drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations: (i) diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or (ii) a diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol/drug abuser (e.g. involuntary ingestion of alcohol/drugs or reaction to a prescribed dosage of one or more drugs).</p>	<p>§160.103: <i>Individually identifiable health information:</i> is information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.</p> <p>§160.103: <i>Protected health information:</i> is individually identifiable health information that is transmitted or maintained in any medium.</p>	<p>42 C.F. R. Part 2 “excepts out” a portion of information that is not given privacy protection under this regulation; HIPAA covers all individually identifiable health information used/disclosed by a covered entity or Business Associate. Programs covered by both must either extend HIPAA coverage to the information excepted out of 42 CFR Part 2 in this provision, or extend the reach of 42 CFR Part 2 to this excepted information.</p>

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<p>§2.13 Confidentiality restrictions. (a) General. The patient records to which these regulations apply may be disclosed/used only as permitted ...and may not otherwise be disclosed/used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.</p>	<p>§164.502(b) Minimum Necessary: (1)When using or disclosing PHI or when requesting PHI from another covered entity, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the purpose of the use, disclosure, or request. (2) This does not apply to: (i) Disclosures to/ requests by a health care provider for treatment; (ii) Uses or disclosures made to the individual, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization; (iii) Disclosures made to the Secretary of HHS; (iv) Uses or disclosures that are required by law, and (v) Uses or disclosures that are required for compliance with applicable requirements of this Subchapter. (p. 82805,82806)</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should continued to follow this provision of 42 CFR Part 2, since it is more stringent than HIPAA.</p>
<p>§2.13 Confidentiality restrictions. (b) Unconditional compliance required. The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.</p>	<p>No comparable provision.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA should follow this provision of 42 CFR Part 2.</p>
<p>§2.13 Confidentiality restrictions. (c) Acknowledging the presence of patients: Responding to requests (1) The presence of an identified patient in a facility/component of a facility which is publicly identified as a place where only alcohol/drug abuse diagnosis, treatment or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgment of the presence of an identified patient in a facility or part of a facility if the facility is not publicly identified as only an alcohol/drug abuse diagnosis, treatment or referral facility, and if the acknowledgment does not reveal that the patient is an alcohol/drug abuser. (2) Any answer to a request for a disclosure of patient records which is not permissible under these</p>	<p>§164.510(a) Use/Disclosure for Facility Directories: (1) Except when an objection is expressed....a covered health care provider may: (i) Use the following PHI to maintain a directory of individuals in its facility: Individual's name;location in the facility; condition described in general terms that does not communicate specific medical information; religious affiliation; and (ii) Disclose for directory purposes such information: to members of the clergy;or except for religious affiliation, to other persons who ask for the individual by name.</p> <p>§164.508(a)(1): Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose PHI without an authorization that is valid under this section. (p. 82811:1)</p>	<p>Generally, providers covered by both 42 CFR Part 2 and HIPAA should follow the former with regard to these provisions. However, HIPAA supersedes the provision in 42 CFR Part 2 which permits acknowledgment of the presence of an identified patient in a facility or part of a facility if the facility is not publicly identified as only an alcohol/drug abuse program and if the acknowledgment does not reveal that the patient is an alcohol/drug abuser. Under HIPAA, this is not permitted unless the individual has been given an opportunity to agree or object to these disclosures.</p>

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<p>regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol/drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol/drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and has never been a patient.</p>		
<p>§2.14 Minor patients. (a) Definition of minor. As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years. (b) State law not requiring parental consent to treatment. If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under Subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay. (c) State law requiring parental consent to treatment.(1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under Subpart C of these</p>	<p>Not originally addressed in final rule, but see recent amendments: (8/02)</p> <p>§164.502: (g)(1)(ii) Implementation specification: unemancipated minors...(A).A covered entity may disclose PHI about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> if the applicable provision of State law or other law, including applicable case law, permits or requires such disclosure, and (B) a covered entity may not disclose PHI about about an unemancipated minor to a parent, guardian, or other person acting <i>in loco parentis</i> if the applicable provision of State law or other law, including applicable case law, prohibits such disclosure.</p>	<p><u>Regulations are consistent:</u> Inasmuch the adoption of recent amendments to HIPAA defer to State law with regard to parental consent/access to records of minors, and 42 CFR Part 2 essentially does the same, with additional more stringent provisions, 42 CFR and State law (MHL §22.11) control.</p>

Federal Law	HIPAA Regulation	Compatability Analysis
<p>regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.</p> <p>(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:(i) The minor has given written consent to the disclosure in accordance with Subpart C of these regulations or (ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section</p> <p>(d) Minor applicant for services lacks capacity for rational choice. Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:</p> <p>(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under Subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and</p> <p>(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.</p>		
<p>§ 2.15 Incompetent and deceased patients.</p> <p>(a) Incompetent patients other than minors (1) Adjudication of incompetence. In the case of a</p>	<p>§164.502(g) (1) :A "personal representative" can fulfill the role of the individual about whom PHI pertains; (2) If, under applicable law, a person has authority to act on behalf of an individual who is an adult or an emancipated minor im making</p>	<p>1. HIPAA acknowledges consent by "personal representatives," defined as</p>

Federal Law	HIPAA Regulation	Compatibility Analysis
<p>patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.</p> <p>(2) No adjudication of incompetency. For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under Subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.</p> <p>(b) Deceased patients</p> <p>(1) Vital statistics. These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.</p> <p>(2) Consent by personal representative. Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.</p>	<p>decisions related to health care, a covered entity must treat such person as a personal representative with respect to PHI relevant to such personal representation.</p> <p>§164.506(a)(3)(i)(A),(B),(C) : In emergency treatment situations, if the covered health care provider is required by law to treat the individual, or if a covered health care provider is unable to obtain consent due to substantial barriers to communication and the covered health provider determines, in its professional judgment, that the patient's consent is inferred by the circumstances, <i>and</i> the covered health care provider attempts to obtain such consent but is unable to obtain such consent, a covered health care provider may use/disclose PHI to carry out treatment, payment, or health care operations without patient consent.</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(g): A covered entity may disclose PHI to a coroner or medical examiner for the purpose of identifying a deceased person, determining cause of death, or other duties as authorized by law. (P. 82816: 1)</p>	<p>persons authorized to make health care decisions for the individual. 42 CFR, however, is both more narrow and more broad than HIPAA in that it requires adjudication that a person is unable to manage his/her own affairs; HIPAA does not. However, HIPAA only permits personal representation if the representative can make health care decisions for the individual, whereas 42 CFR Part 2 uses the term "manage affairs," so in this respect HIPAA prevails.</p> <p>2. HIPAA would permit provisions of 42 CFR Part 2 which allow a program director to use PHI for payment purposes without patient consent for the sole purpose of seeking payment, under the "substantial barriers to communication" exception. HIPAA would permit use/disclosure in these circumstances for treatment and health care operations purposes as well, but 42 CFR Part 2 would not, and hence that aspect of the latter regulation would prevail.</p> <p>3. HIPAA and 42 CFR Part 2 are generally consistent with regard to disclosures about decedents for purposes of investigating cause of death; programs covered by both should follow 42 CFR Part 2. It should be noted, however, that HIPAA contains no provisions with regard to who may consent to the release of PHI upon a person's death; therefore, it is not clear if the provisions under 42 CFR Part 2 allowing such consent by an executor, personal representative, spouse or family member are permissible.</p>

Federal Law	HIPAA Regulation	Compatibility Analysis
<p>§ 2.16 Security for written records. (a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and (b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.</p>	<p>§164.530(c)(1): Safeguards: A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI.(2) A covered entity must reasonably safeguard PHI from any intentional use/disclosure that is in violation of these standards, implementation specifications, or other requirements of this subpart.</p>	<p>The security provisions of 42 CFR Part 2 apply only to written records. Once an entity is covered by HIPAA, the privacy protections apply to records created/stored/transmitted in any medium. Therefore, HIPAA would supersede 42 CFR Part 2 and programs covered by both should comply with the HIPAA safeguard requirements.</p>
<p>§ 2.17 Undercover agents and informants. (a) Restrictions on placement. Except as specifically authorized by a court order granted under § 2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant. (b) Restriction on use of information. No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.</p>	<p>No comparable provision</p>	<p>Programs covered by both HIPAA and 42 CFR Part 2 are bound by 42 CFR Part 2 with regard to this provision.</p>
<p>§ 2.18 Restrictions on the use of identification cards. No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.</p>	<p>No comparable provision</p>	<p>Programs covered by both HIPAA and 42 CFR Part 2 are bound by 42 CFR Part 2 with regard to this provision</p>

Federal Law	HIPAA Regulation	Compatability Analysis
<p>§ 2.19 Disposition of records by discontinued programs.</p> <p>(a) General. If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless--</p> <p>(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or</p> <p>(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.</p> <p>(b) Procedure where retention period required by law. If paragraph (a)(2) of this section applies, the records must be:</p> <p>(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]"; and</p> <p>(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.</p>	<p>§164.530(c)(1): Safeguards: A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI.(2) A covered entity must reasonably safeguard PHI from any intentional use/disclosure that is in violation of these standards, implementation specifications, or other requirements of this subpart.</p>	<p>It would appear that a program covered by both HIPAA and 42 CFR Part 2 could comply with both provisions; however, applicable provisions of the HIPAA security regulation, when finalized, may impact this analysis.</p>
§2.21 Relationship to Federal statutes	Covered entities subject to these rules are also subject to other statutes and	As the federal research statutes

Federal Law	HIPAA Regulation	Compatability Analysis
<p>protecting research subjects against compulsory disclosure of their identity.(a) Research privilege description. There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act...and implementing regulations at 42 CFR Part 2a); or section 502(c) of the Controlled Substances Act (21 USC 872(c) and the implementing regulations at 21 CFR 1316.21. These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.(b) Effect of concurrent coverage. These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under Subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g)to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with Subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21</p>	<p>regulations. Thus, covered entities will need to determine how the privacy regulation will affect their ability to comply with these other laws. ..Ordinarily, later, general statutes will not repeal the special provisions of an earlier, specific statute. In some cases, when a later, general statute creates an irreconcilable conflict or is manifestly inconsistent with the earlier, specific statute in a manner that represents a clear and manifest Congressional intent to repeal the earlier statute, courts will find that the later statute repeals the earlier statute by implication. In these cases, the latest legislative action may prevail and repeal the prior law, but only to the extent of the conflict. (Preamble, p. 82481)</p>	<p>identified in 42 CFR Part 2 do not appear inconsistent with, or contrary to the HIPAA privacy regulations, providers subject to both HIPAA and 42 CFR Part 2 should continue to follow this provision.</p>

Federal Law	HIPAA Regulation	Compatability Analysis
CFR 291.505(g)as a defense to a subpoena for that information.		
<p>§2.22 Notice to patients of Federal confidentiality requirements.(a) Notice required. At the time of admission or as soon thereafter as the patient is capable of rational communication. each program shall:(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and (2) Give to the patient a summary in writing of the Federal law and regulations.</p> <p>(b) Required elements of written summary. The written summary of the Federal law and regulations must include:</p> <p>(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.</p> <p>(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.</p> <p>(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.(5) A citation to the Federal law and regulations.(c) Program options. The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of</p>	<p>§164.520 Notice of privacy practices for PHI</p> <p>1. An individual has a right to adequate notice of the uses and disclosures of PHI that may be made by the covered entity, and the individual's rights and the covered entity's legal duties with respect to PHI.</p> <p>2. The notice must contain the following statement as a header or otherwise prominently displayed: THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.</p> <p>3. The notice must be written in plain language and contain: (1) a description, including at least 1 example, of the types of uses/disclosures that the covered entity is permitted to make for treatment, payment & health care operations purposes; (2) a description of each of the other purposes for which the covered entity is permitted/required to use/disclose PHI w/out the person's consent/authorization; (3) if a use/disclosure is prohibited or materially limited by other applicable law, the description of such use/disclosure must reflect the more stringent; (4) for each purpose described the description must include sufficient detail to place the person on notice of the uses/disclosures that are permitted/required by HIPAA and other applicable law; (5) a statement that other uses/disclosures will be made only with the person's written authorization and that the individual may revoke such authorization.</p> <p>4. If the covered entity intends to engage in any of the following, the description must include a separate statement, as applicable, that (1) the covered entity may contact the individual to provide appointment reminders; (2) the covered entity may contact the individual to raise funds; (3) a group health plan..may disclose PHI to the sponsor.</p> <p>5. The notice must contain a statement of the individual's rights with respect to PHI and a brief description of how the person can exercise those rights (i.e., right to request restrictions, right to receive confidential communications, right to inspect/copy PHI, right to amend PHI, right to receive accounting of disclosures, and right to receive paper copy of the notice, if notice is received electronically).</p> <p>6. The notice must contain covered entity requirements (i.e, statement that the covered entity is required by law to maintain the privacy of PHI and to provide the notice of its legal duties and privacy practices; a statement that the covered entity is required to abide by the terms of the notice; in order for the covered entity to apply a change in its privacy practices, a statement that it reserves the right to change the terms of its notice and to make the new notice provision effective for all PHI it maintains (must also describe how it will provide persons with a new notice).</p> <p>7. Complaints. The notice must contain a statement that individuals may complain to the covered entity and the Secretary of HHS if they believe their privacy rights have been violated; a brief description of how to file a complaint with the covered</p>	<p>It would appear that a program covered by both HIPAA and 42 CFR Part 2 could comply with both provisions; however,extensive revision of the notice required under 42 CFR is required in order to comport with the HIPAA notice requirements.</p>

Federal Law	HIPAA Regulation	Compatability Analysis
<p>confidentiality of alcohol and drug abuse patient records. (d) Sample notice....(is provided)</p>	<p>entity; and advise of nonretaliation for filing a complaint. 8. Contact. The notice must contain a contact name, or title, and telephone # of a person/office to contact for further information. 9. Effective date. The notice must contain the date on which the notice is first in effect, which cannot be earlier than the date on which it is printed/published. 10. Provisions for optional contents are also included. 11. A covered health care provider with a direct treatment relationship with the patient must provide the notice no later than the date of first service delivery, and, except in an emergency situation, make a good faith effort to obtain a written acknowledgment. 12. Whenever the notice is revised, the notice must be made available upon request on or after the effective date of the revision and promptly comply with the acknowledgment requirements. 13. Electronic notice is permitted.</p>	
<p>§ 2.23 Patient access and restrictions on use. (a) Patient access not prohibited. These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient. (b) Restriction on use of information. Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement. §164.524(c)(1): The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the PHI about them in designated record sets. §164.524(c)(2)(i): The covered entity must provide the individual with access to the PHI in the form or format requested by the individual, if it is readily producible in such form or format; if not, a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.</p>	<p>It would appear that a program covered by both HIPAA and 42 CFR Part 2 could comply with both provisions; however, HIPAA provides an articulated right to access while 42 CFR Part 2 simply indicates a program is not prohibited from providing such access. Additional provisions of HIPAA give an individual the right to request access to information in a specific format. Therefore, a program covered by both regulations should refer to both to determine how to respond to requests for access to a record by a patient and to ensure compliance with patient rights under HIPAA.</p>
<p>§ 2.31 Form of written consent. (a) Required elements. A written consent to a disclosure under these regulations must include: (1) The specific name or general designation of the program or person permitted to make the disclosure; (2) The name or title of the individual or the name of the organization to which disclosure is to be made. (3) The name of the patient.</p>	<p>§164.506(c): Consent: Content requirements. A consent under this section must be in plain language and: (1) Inform the individual that PHI may be used/disclosed to carry out treatment, payment, and health care operations; (2) refer the individual to the notice required by §164.520 for a more complete description of such uses/disclosures and state that the individual has the right to review the notice prior to signing the consent; (3) if the covered entity has reserved the right to change its privacy practices that are described in the notice in accordance with §164.520(b)(1)(v)(C), state that the terms of its notice may change and describe how the individual may obtain a revised notice; (4) state that: (i) the individual has</p>	<p>With a limited exception, programs covered by both 42 CFR Part 2 and HIPAA should follow 42 CFR Part 2 with regard to form of consent. However, since a "consent" under 42 CFR Part 2 more closely resembles a HIPAA "authorization" than a HIPAA "consent," a program covered by both needs to ensure that its consent form</p>

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<p>(4) The purpose of the disclosure.</p> <p>(5) How much and what kind of information is to be disclosed.</p> <p>(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.(7) The date on which the consent is signed.</p> <p>(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is 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</p> <p>(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.</p> <p>(b) Sample consent form. The following form complies with paragraph (a) of this section, but other elements may be added.1. I (name of patient) ()Request "()" Authorize:2. (name or general designation of program which is to make the disclosure)</p> <p>3. To disclose: (kind and amount of information to be disclosed)</p> <p>4. To: (name or title of the person or organization to which disclosure is to be made)5. For (purpose of the disclosure)6. Date (on which this consent is signed)7. Signature of patient 8. Signature of parent or guardian (where required)</p> <p>9. Signature of person authorized to sign in lieu of the patient (where required)</p> <p>10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already</p>	<p>the right to request that the covered entity restrict how PHI is used/disclosed to carry out treatment, payment, or health care operations; (ii) the covered entity is not required to agree to requested restrictions; and (iii) if the covered entity agrees to a requested restriction, the restriction is binding on the covered entity; (5) state that the individual has the right to revoke the consent in writing, except to the extent the covered entity has acted in reliance on it; and (6) be signed by the individual and dated. (Note: Recent amendments eliminate this requirement).</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.508(c): Authorization: Core elements and requirements: A valid authorization under this section must contain at least the following elements: (i) a description of the information to be used/disclosed that identifies the information in a specific and meaningful fashion (ii) the name/other specific identification of the person(s) or class of person authorized to make the requested use/disclosure; (iii) the name/other specific identification of the person(s) or class of persons to whom the covered entity may make the requested use/disclosure; (iv) an expiration date/expiration event that relates to the individual/purpose of use/disclosure; (v) a statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization; (vi) a statement that information used/disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by HIPAA; (vii) signature of individual and date; and (viii) if the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual.</p> <p>(2) <u>Required statements.</u> In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:</p> <p>(i) The individual's right to revoke the authorization in writing, and either:</p> <p>(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or</p> <p>(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by section 164.520, a reference to the covered entity's notice.</p> <p>(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:</p> <p>(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or</p>	<p>includes all of the elements necessary for a valid HIPAA authorization for all uses/disclosures of PHI for which a patient authorization is needed under HIPAA.</p> <p>A 42 CFR Part 2 "consent" is more stringent than a HIPAA consent, in light of the amount of detail it requires. Furthermore, the "minimum necessary" rule, which does not apply to HIPAA uses/disclosures for payment, and health care operations purposes, continues to apply to all 42 CFR Part 2 uses and disclosures, with no exceptions. Therefore, the "minimum necessary" rule of 42 CFR Part 2 should continue to be applied in all uses/disclosures for which a consent is needed under 42 CFR Part 2 and a consent/authorization is needed under HIPAA.</p> <p>42 CFR Part 2 does not require any type of consent for use/disclosure of PHI for treatment purposes; this is consistent with the recent amendments to HIPAA. Thus, the two sets of regulations are consistent on this point.</p>

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<p>taken action in reliance on it. If not previously revoked, this consent will terminate upon:</p> <p>(specific date, event, or condition)(c) Expired, deficient, or false consent. A disclosure may not be made on the basis of a consent which:</p> <p>(1) Has expired;</p> <p>(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;</p> <p>(3) Is known to have been revoked; or</p> <p>(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.</p>	<p>(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.</p> <p>(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this rule.</p> <p>(3) <u>Plain language requirement.</u> The authorization must be written in plain language.</p> <p>(4) <u>Copy to the individual.</u> If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.</p> <p><i>revised 8/02</i></p>	

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<p>§ 2.32 Prohibition on redisclosure.</p> <p><i>Notice to accompany disclosure.</i> Each disclosure made with the patient's written consent must be accompanied by the following written statement:</p> <p>This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.</p>	<p>No comparable provision.</p>	<p>Programs covered by both sets of federal regulations should continue to follow 42 CFR Part 2 with regard to this requirement.</p>
<p>§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.</p> <p>(a) Definitions. For purposes of this section: Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.</p> <p>Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.</p> <p>Maintenance treatment means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other</p>	<p>§160.203 General rule and exceptions</p> <p>A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law . This general rule applies, except if one or more of the following conditions is met: (a) A determination is made by the Secretary under §160.204 that the provision of State law:...(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 USC 802), or that is deemed a controlled substance by State law.</p>	<p>Although HIPAA appears to require a written determination by the Secretary, it appears likely that reports to the methadone registry will continue to be permitted under HIPAA in accordance with this provision.</p>

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<p>morphine-like drugs.</p> <p>Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.</p> <p>(b) Restrictions on disclosure. A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:</p> <p>(1) The disclosure is made when:</p> <ul style="list-style-type: none"> (i) The patient is accepted for treatment; (ii) The type or dosage of the drug is changed; or (iii) The treatment is interrupted, resumed or terminated. <p>(2) The disclosure is limited to:</p> <ul style="list-style-type: none"> (i) Patient identifying information; (ii) Type and dosage of the drug; and (iii) Relevant dates. <p>(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:</p> <ul style="list-style-type: none"> (i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and (ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program. <p>(c) Use of information limited to prevention of multiple enrollments. A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a</p>		

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<p>court order under Subpart E of these regulations.</p> <p>(d) Permitted disclosure by a central registry to prevent a multiple enrollment. When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose--</p> <p>(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and</p> <p>(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.</p> <p>(e) Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment. A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment</p> <p>NYS Mental Hygiene Law §19.16 Methadone registry. The office shall establish and maintain, either directly or through contract, a central registry for purposes of preventing multiple enrollment in methadone programs. The office shall require all methadone programs to utilize such registry and shall have the power to assess methadone programs such fees as are necessary and appropriate.</p>		
<p>§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.</p>	<p>§164.501: <i>Required by law</i> means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative</p>	<p>If the disclosures back to a court regarding treatment are mandated in a court order, HIPAA would permit these disclosures without patient consent.</p>

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<p>(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the 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:</p> <p>(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 posttrial release, probation or parole officers responsible for supervision of the patient); and</p> <p>(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) 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:</p> <p>(1) The anticipated length of the treatment;</p> <p>(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</p> <p>(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.</p> <p>(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.</p> <p>(d) Restrictions on redisclosure and use. A person who receives patient information under</p>	<p>body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p>	<p>In contrast, 42 CFR Part 2 would require patient consent for such disclosures, but does not permit revocation of such consent until a specified date or event. Since the provision requiring consent for these disclosures is more stringent, this part of 42 CFR Part 2 would apply.</p> <p>However, under HIPAA, authorizations are revocable by the patient at any time. Compliance with both HIPAA and 42 CFR Part 2 would require providers to utilize consents/authorizations that meet the requirements of both. Therefore, it would appear that criminal justice consents, like any HIPAA consent/authorization, would be revocable by patients at any time.</p>

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<p>this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.</p>		
<p>§ 2.51 Medical emergencies.</p> <p>(a) General Rule. Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention. (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 program shall document the disclosure in the patient's records, setting forth in writing:</p> <p>(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;</p> <p>(2) The name of the individual making the disclosure;</p> <p>(3) The date and time of the disclosure;</p> <p>and</p> <p>(4) The nature of the emergency (or error, if the report was to FDA).</p>	<p>§164.506(a)(3)(i)(A): A covered health care provider may use/disclose PHI without patient consent in emergency treatment situations, if the covered health care provider attempts to obtain consent as soon as reasonably practical after the delivery of treatment.</p> <p>Note recent amendments to this requirement :</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p> <p>§164.512(b): A covered entity may disclose PHI for the public health activities and purposes described in this paragraph to: (ii) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect..., (iii) a person subject to the jurisdiction of the FDA (A) to report adverse events....</p> <p>§164.512(j): A covered entity may, consistent with applicable law and standards of ethical conduct, use/disclose PHI if it believes, in good faith, that the use/disclosure (i)(A) is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and (B) is to a person(s) reasonably able to prevent/lessen the threat.</p>	<p>In general, programs covered by 42 CFR Part 2 and HIPAA can continue to follow the provisions of 42 CFR Part 2 with regard to disclosures for medical emergencies.</p>

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<p>§ 2.52 Research activities.</p> <p>(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:</p> <p>(1) Is qualified to conduct the research;</p> <p>(2) Has a research protocol under which the patient identifying information:</p> <p>(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and</p> <p>(ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and</p> <p>(3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:</p> <p>(i) The rights and welfare of patients will be adequately protected; and</p> <p>(ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.</p> <p>(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.</p>	<p>§164.512(h): A covered entity may use/disclose PHI for research, regardless of the source of the funding of the research, provided that (i) Board approval of a waiver of authorization: The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use/disclosure of PHI has been approved by either (A) an IRB established in accordance with....(B) a privacy board that: (1) has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests; (2) includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities and; (3) does not have any member participating in a review of any project in which the member has a conflict of interest....</p> <p>(2) Documentation of waiver approval. For a use/disclosure to be permitted,...documentation must include.. li) Waiver criteria: A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria: (A) the use/disclosure of PHI involves no more than minimal risk to the individuals;(B) the alteration/waiver will not adversely affect the privacy rights/welfare of the individuals; (C) the research could not practicably be conducted without the alteration/waiver; (D) the research could not practicably be conducted without access to/use of the PHI; (E) the privacy risks to individuals whose PHI are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research; (F) there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and (H) there is adequate written assurances that the PHI will not be reused/disclosed to any person/entity except as required by law, for authorized oversight of the research project, or for other research for which the use/disclosure of the PHI would be permitted by this subpart.</p>	<p>In this instance, HIPAA is generally more restrictive on use/disclosure of PHI for research purposes. Therefore, programs covered by both 42 CFR Part 2 and HIPAA should refer to HIPAA in determining how to respond to requests for PHI for research purposes. It should be noted, however, the 42 CFR Part 2 permits redisclosure of PHI <u>only back to the program from which that information was obtained</u> and may not identify any individual patient in any report of that research or otherwise disclose patient identities; this requirement is more restrictive than HIPAA and thus would prevail.</p>
<p>§ 2.53 Audit and evaluation activities.</p> <p>(a) Records not copied or removed. If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure</p>	<p>§164.501: Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory...or a person or entity operating under a grant of authority from or contract with such public agency....that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p>	<p>With regard to audit and evaluation activities, 42 CFR Part 2 is generally more restrictive on use/disclosure of PHI for these purposes. Therefore, programs covered by both 42 CFR Part 2 and HIPAA should refer to 42 CFR Part 2 in determining how to respond to</p>

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<p>and use in paragraph (d) of this section and who:(1) Performs the audit or evaluation activity on behalf of:</p> <p>(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review; or(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.</p> <p>(b) Copying or removal of records. Records containing patient identifying information may be copied or removed from program premises by any person who:</p> <p>(1) Agrees in writing to:(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and</p> <p>(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and</p> <p>(2) Performs the audit or evaluation activity on behalf of:</p> <p>(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review.</p>	<p>§164.512(d) A covered entity may disclose PHI to a health oversight agency for oversight activities authorized by law.</p> <p>§164.506 A covered entity must obtain the consent of a patient to use or disclose PHI for treatment, payment, or health care operations purposes (p.82810:1)</p> <p>Note: Recent amendments eliminate this requirement.</p> <p>§164.506(c):(1) A covered entity may use/disclose PHI for its own treatment, payment, or health care operations. (2) A covered entity may disclose PHI for treatment activities of a health care provider. (3) A covered entity may disclose PHI to another covered entity or health care provider for the payment activities of the entity that receives the information.... <i>revised 8/02</i></p>	<p>requests for PHI for audit and evaluation activities.</p>
<p>(c) Medicare or Medicaid audit or evaluation.</p> <p>(1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative</p>		

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<p>investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.</p> <p>(2) Consistent with the definition of program in § 2.11, program 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)(1) of this section.(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a quality improvement organization which obtains the information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.</p> <p>(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.</p> <p>(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 program from which it was obtained and 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 of these regulations</p>		
<p>§ 2.61 Legal effect of order.</p>	<p>§164.501: <i>Required by law:</i> a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law;</p>	<p>Because 42 CFR Part 2 is more strict than HIPAA in specifying the necessary</p>

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<p>(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. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. 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 these regulations.</p> <p>(b) Examples.</p> <p>(1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.</p> <p>(2) An authorizing court order is entered under these regulations, but the person authorized 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 authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.</p>	<p>includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p>	<p>content of court orders under which PHI can be disclosed, programs covered by both 42 CFR Part 2 and HIPAA should continue to refer to the former when releasing PHI pursuant to court order.</p>
<p>§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.</p> <p>A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government</p>	<p>Because 42 CFR Part 2 is more strict than HIPAA in restricting the ability of court orders to authorize disclosure of PHI in certain circumstances, programs covered by both 42 CFR Part 2 and HIPAA should continue to refer to the former when considering releases of PHI obtained in the course of research,</p>

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<p>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.</p>	<p>program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p>	<p>audit, or evaluation activities in the context of criminal investigations of patients.</p>
<p>§ 2.63 Confidential communications.</p> <p>(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:</p> <p>(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;</p> <p>(2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, 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</p> <p>(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.</p>	<p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p>	<p>In limiting the scope of authorizing court orders, 42 CFR Part 2 is more strict than HIPAA, which provides for no such limitations. Therefore, for programs covered by both regulations, 42 CFR Part 2 shall continue to control in this circumstance.</p>
<p>§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.</p> <p>(a) Application. An order authorizing the disclosure of patient records for purposes other</p>	<p>No comparable provision.</p> <p><i>but see:</i></p> <p>§164.501: Required by law: a mandate contained in law that compels a covered</p>	<p>Programs covered by both HIPAA and 42 CFR Part 2 should continue to refer to 42 CFR Part 2 with regard to the procedure/criteria for authorizing court orders for disclosures for noncriminal</p>

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<p>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 it appears 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 a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.</p> <p>(b) Notice. The patient and the person holding the records from whom disclosure is sought must be given:</p> <p>(1) Adequate notice in a manner which will not disclose patient identifying information to other persons: and</p> <p>(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.</p> <p>(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 these regulations. 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:</p> <p>(1) Other ways of obtaining the information are</p>	<p>entity to make a use/disclosure of PHI and that is enforceable in a court of law; includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p>	<p>purposes.</p>

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<p>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.</p>		
<p>§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records. (a) Application. (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) 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 program or the person holding the records (or agents or employees of the program or person) in which it appears 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</p>	<p>No comparable provision. <i>but see:</i></p> <p>§160.501:Law enforcement official means an officer or employee of any agency or authority, of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (1) investigate or conduct an official inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.</p> <p>§164.512(f)(1): A covered entity may disclose PHI for a law enforcement purpose to a law enforcement official...(i) in compliance with and as limited by the relevant requirements of:(A) a court order or court-ordered subpoena or summons issued by a judicial officer; (B) a grand jury subpoena; or(C) an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:(1) the information sought is relevant and material to a legitimate law enforcement inquiry;(2)the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and(3)de-identified information could not reasonably be used.</p> <p>§164.501: Required by law: a mandate contained in law that compels a covered entity to make a use/disclosure of PHI and that is enforceable in a court of law;</p>	<p>Programs covered by both HIPAA and 42 CFR Part 2 should continue to refer to 42 CFR Part 2 with regard to the procedure/criteria for authorizing court orders for disclosures for prosecutorial purposes.</p>

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<p>unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) 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 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.</p> <p>(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 of these regulations.</p> <p>(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.</p> <p>(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.65 of these regulations.</p>	<p>includes, but is not limited to, court orders and court ordered warrants, subpoenas or summons issued by a court, grand jury, a gov'tal...inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation...; and statutes/ regulations that require the production of information, including statutes/ regulations that require such information if payment is sought under a government program providing public benefits.</p> <p>§164.512(a): A covered entity may use/ disclose PHI to the extent that such use/ disclosure is required by law and the use/ disclosure complies with and is limited to the relevant requirements of such law.</p>	
<p>§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.</p> <p>(a) Application. A court order authorizing the placement of an undercover agent or informant in a 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 program are engaged in criminal misconduct.</p> <p>(b) Notice. The program director must be given</p>	<p>No comparable provisions.</p>	<p>Programs covered by both HIPAA and 42 CFR Part 2 should continue to refer to 42 CFR Part 2 with regard to the procedure/criteria for orders authorizing the use of undercover agents and informants.</p>

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<p>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), unless the application asserts a belief that:</p> <p>(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or</p> <p>(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.</p> <p>(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:</p> <p>(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;</p> <p>(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and</p> <p>(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the 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 program must:</p> <p>(1) Specifically authorize the placement of an undercover agent or an informant;</p> <p>(2) Limit the total period of the placement to six months;</p> <p>(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and</p> <p>(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any</p>		

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<p>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.</p> <p>(e) Limitation on use of information. No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.65 of these regulations.</p>		
<p>Patient Access to Records</p> <p>Not addressed in 42 CFR Part 2.</p>	<p>§164.524(b)(1): The covered entity must permit an individual to request access to inspect or obtain a copy of the PHI about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.</p> <p>§164.524(b)(2): The covered entity must act on a request for access no later than 30 days after receipt of the request.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA must follow the HIPAA rules in regard to this requirement.</p>
<p>Right to request Restrictions</p> <p>Not addressed in 42 CFR Part 2.</p>	<p>§164.522 (a)(1) Right to request restrictions. A covered entity must permit an individual to request that the covered entity restrict (1) uses/disclosures of PHI about the individual to carry out treatment, payment and health care operations and (2) disclosures of PHI for involvement in the individual's care and notification purposes. A covered entity does not have to agree to these restrictions.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA must follow the HIPAA rules in regard to this requirement.</p>
<p>Right to request Accountings</p> <p>Not addressed in 42 CFR Part 2.</p>	<p>§164.528 (a)(1) Right to request accountings. An individual has a right to receive an accounting of disclosures of PHI made by a covered entity in the 6 years prior to the date on which an accounting is requested, except for disclosures: (1) to carry out treatment, payment, and health care operations; (2) to the individuals themselves; (3) that are made for national security or intelligence purposes; (4) that are related to certain custodial situations; (5) to correctional institutions and law enforcement officials; and (6) which occurred prior to the compliance date for the covered entity.</p> <p>§164.528 (c): The covered entity must act on the individual's request for an accounting no later than 60 days after receipt of such request by providing the accounting or requesting an extension of no more than 30 days. The first accounting must be provided without charge, and thereafter a reasonable, cost-based fee for each subsequent accounting may be charged if the individual is informed in advance of the fee and an opportunity to modify the request to reduce or avoid the fee.</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA must follow the HIPAA rules in regard to this requirement.</p>

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	<p>§164.528 (d): Documentation. A covered entity must retain documentation of the information required to be included in an accounting, the written accounting provided to the individual, and titles of persons or responsible officers who process/receive accountings.</p>	
<p>Administrative Requirements:</p> <p>Not addressed, (or in the case of safeguard requirements, not adequately addressed), in 42 CFR Part 2.</p>	<p>§164.530 (a)(1): Personnel Designations: A covered entity must designate a privacy official who is responsible for the development and implementation of the policies/procedures of the entity.</p> <p>§164.530 (a)(2) Documentation: A covered entity must document the required personnel designations.</p> <p>§164.530 (a)(3) Training: A covered entity must train all members of its workforce on the policies/procedures with respect to PHI required by HIPAA, as necessary and appropriate to carry out their functions within the covered entity. The workforce must be trained prior to the compliance date; new members must be trained within a reasonable time after joining the workforce..... Such training must be documented.</p> <p>§164.530 (c) Safeguards. A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI...</p> <p>§164.530 (d)(1): Complaints. A covered entity must provide a process for individuals to make complaints concerning: (1) the covered entity's policies and procedures required by HIPAA and (2) its compliance with such policies and procedures or the requirements of HIPAA.</p> <p>§164.530 (d)(2) Documentation of complaints: A covered entity must document all complaints received, as well as their disposition.</p> <p>§164.530 (e)(1),(2) Sanctions: A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with HIPAA... Those sanctions must be documented.</p> <p>§164.530 (f): Mitigation: A covered entity must mitigate, to the extent practicable, any harmful effects known to the covered entity of a use/disclosure of PHI in violation of its policies/procedures or HIPAA by the covered entity or its business associate.</p> <p>§164.530 (g) Retaliatory acts: A covered entity may not intimidate, threaten, coerce, discriminate against, or take retaliatory action against any individual for exercising his/her rights or for filing a complaint with HHS...</p> <p>§164.530 (h): Waiver: A covered entity may not require individuals to waive their rights to file complaints or any other rights under HIPAA as a condition of provision</p>	<p>Programs covered by both 42 CFR Part 2 and HIPAA must follow the HIPAA rules in regard to these requirements.</p>

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	<p>of treatment, payment, enrollment in a health plan, or eligibility for benefits.</p> <p>§164.530 (i)(1),(2),(3),(4) Policies and procedures: A covered entity must implement policies and procedures with respect to PHI designed to comply with the requirements of HIPAA.... Such policies/procedures must be changed as necessary to comply with changes in the law ..must document and implement the revised policies/procedures promptly....and must revise its Notice of Privacy Practices.</p> <p>§164.530 (j)(1),(2) Retention of policies: A covered entity must maintain the required policies/procedures in written or electronic form, copies of communications HIPAA requires, and records of any action, activity, or designation HIPAA requires to be documented. Such documentation must be retained for 6 years from date of creation or date last in effect, whichever is later.</p>	