

Appendix D

Policies, Standing Orders, and HIPAA



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Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission

The guidelines in this document were developed to help hospitals establish policies and standing orders in their labor and delivery (L&D) and newborn units.

During 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in children which includes the recommendation to administer hepatitis B vaccine to **all newborns before hospital discharge**. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the birth dose recommendation. To obtain a copy, go to www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:

- 1 Administer hepatitis B vaccine to **ALL newborns** before they are discharged from the hospital.
- 2 Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.

Admission orders and procedures for women admitted to a birthing facility

For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:

- 1 Examine a copy of the *original* laboratory report of the pregnant woman's HBsAg¹ test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
- 2 Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record (or have a link to the mother's HBsAg test result).
- 3 If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis – both hepatitis B immune globulin (HBIG) and hepatitis B vaccine – within 12 hours of birth.
- 4 Perform a repeat blood test for HBsAg¹ if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-

drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing

- 5 Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For pregnant women who do not have an HBsAg lab report on their prenatal record, do the following:

- 1 Perform HBsAg¹ testing ASAP on women who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
- 2 Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

Admission orders and procedures for newborns

Hospital procedures to follow for ALL newborns

- 1 Review a copy of the mother's *original* HBsAg¹ lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
- 2 Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2 kg (4.4 lb), see the descriptions below and footnotes 2, 5, 6.
- 3 Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement (available at www.immunize.org/vis).

For newborns of HBsAg-negative mothers

- 1 Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before hospital discharge to **all** newborns weighing 2 kg (4.4 lb) or more at birth.^{2,3,4}
- 2 Document the hepatitis B vaccine dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
- 3 Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.

For newborns of mothers with unknown HBsAg status, do the following:

- 1 Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.^{3,5} Do not wait for test results to return before giving this dose of vaccine.
- 2 Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, and site of administration, as well as the vaccine lot number.

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- 3 Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.
 - 4 Confirm that the laboratory has received blood for the mother's HBsAg¹ test.
 - 5 Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
 - 6 If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
 - 7 If the laboratory test indicates the mother's HBsAg¹ test result is positive, do the following:
 - a Administer HBIG (0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)
 - b Document the HBIG dose in the newborn's medical record. There is little benefit in administering HBIG to the newborn if more than 7 days have elapsed since birth.
 - c Alert the mother's and newborn's physician(s) of the test result.
 - d Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.
 - 8 If the newborn must be discharged before the mother's HBsAg result is known:
 - a Document the parents' contact information (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed for the infant.
 - b Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
 - c Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.
- 7 Provide advice to the mother. Tell her the following:
 - a That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
 - b That it is critically important for the protection of her baby's health that the baby receives the full hepatitis B vaccine series on the recommended schedule;
 - c That blood tests (HBsAg and antibody to hepatitis B surface antigen [anti-HBs]) need to be drawn from the baby 1–2 months after completion of the 3- or 4-dose hepatitis B vaccine series and also no earlier than 9–12 months of age to determine if the child developed a protective immune response to vaccination or needs additional management⁷;
 - d About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
 - e That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is a candidate for antiviral treatment.

FOOTNOTES

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg (4.4 lb) at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at www.immunize.org/vis.
4. According to the CDC recommendations, exceptions to administering the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If the hepatitis B vaccine birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the infant's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Infants who do not receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.
5. An infant weighing less than 2 kg (4.4 lb) whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg (4.4 lb) whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
7. The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection (see "Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers," *MMWR*, 2015;64: 1118–20).

For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose," visit www.immunize.org/catg.d/p2131.pdf.

For newborns of HBsAg-positive mothers

- 1 Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine^{3,6} (0.5 mL, IM) at separate injection sites within 12 hours of birth.
- 2 Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
- 3 Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
- 4 Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
- 5 Obtain the name, address, and phone number of the newborn's primary care provider.
- 6 Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination as well as postvaccination testing of the infant for both HBsAg and antibody to HBsAg (anti-HBs) after completion of the hepatitis B vaccine series to assess the hepatitis B status of the infant following vaccination.

Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

Routine orders for all newborns

- 1 Review a copy of the mother's original lab report to ensure that the correct serologic test (HBsAg) was ordered and that it was ordered during this pregnancy. Perform a repeat HBsAg blood test on the pregnant woman (mother) if she was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.
- 2 Determine if the newborn is high risk and needs immediate postexposure prophylaxis within 12 hours of birth. The infant is high risk if the mother's HBsAg status is positive or unknown.

For routine newborn hepatitis B vaccination: the mother is HBsAg negative

- 1 Administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, intramuscular (IM), in anterolateral thigh no later than hospital discharge. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. Give the parent a record of the vaccination. If parent unwilling to give consent, notify physician ASAP. Document vaccine administration or vaccine refusal in hospital record.

For highest-risk infants: the mother is HBsAg positive

- 1 Administer Hepatitis B Immune Globulin (HBIG) 0.5 mL, IM, in anterolateral thigh in the delivery room or ASAP within 12 hours of birth. Document HBIG administration in hospital record. Give parent a record of the HBIG dose.
- 2 At same time and in opposite anterolateral thigh, administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, IM, ASAP within 12 hours of birth. Document vaccine administration in hospital record. Give parent a record of the vaccination.
- 3 Prior to administering both HBIG and hepatitis B vaccine, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. If parent unwilling to give consent, notify physician ASAP. Consider notifying Child Protective Services if parent continues to refuse despite discussion with physician.
- 4 Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
- 5 Obtain the name, address, and phone number of the newborn's primary care provider.
- 6 Notify primary care provider of newborn's birth, the date and time that HBIG and hepatitis B vaccine doses were administered, and the importance of additional on-time vaccination (infants weighing less than 2 kg (4.4 lbs) will require 4 doses of vaccine as the first dose does not "count") and postvaccination testing of the infant for HBsAg and antiHBs (antibody to HBsAg) 1–2 months after completion of the hepatitis B vaccine series and no earlier than when the infant is 9–12 months of age.



NOTE: The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection.

- 7 Provide advice to the mother. Tell her the following:
 - a That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
 - b It is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;

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- c Blood tests (HBsAg and anti-HBs) will need to be obtained from the infant 1–2 months after completion of the hepatitis B vaccine series (at 9–12 months of age) to determine if the infant developed a protective immune response to vaccination or needs additional management;
- d About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
- e She and other infected contacts need to have medical evaluations for chronic hepatitis B, including assessment to determine if they are candidates for antiviral treatment.

For high-risk infants: the mother's HBsAg status is unknown

- 1 Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth. For infants weighing less than 2 kg (4.4 lbs) at birth, also administer hepatitis B immune globulin (HBIG 0.5 mL, IM) within 12 hours. Do not wait for test results to return before giving this dose of vaccine (and HBIG for infants weighing less than 2 kg [4.4 lb]). Document vaccine administration in the hospital record. Give the parent a record of the vaccination.
- 2 Confirm that the laboratory has received blood for the mother's HBsAg test.
- 3 Verify when the mother's HBsAg result will be available and that it will be reported to the newborn unit ASAP.
- 4 If the laboratory test indicates the mother's HBsAg test result is positive, do the following:
 - a Administer HBIG 0.5 mL, IM, ASAP to the newborn weighing 2 kg (4.4 lb) or more. (Those weighing less than 2 kg (4.4 lb) at birth should have already received HBIG.) (Hepatitis B vaccine should have been given within 12 hours of birth to all infants of mothers with unknown HBsAg status.)
 - b Follow steps 4–7 of the previous section (see “For highest-risk infants: the mother is HBsAg positive”).

REFERENCES

1. *A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Part 1: Immunization of Infants, Children and Adolescents.* MMWR, December 23, 2005, Vol. 54(RR-16):1-39, at www.cdc.gov/mmwr/pdf/rr/rr5416.pdf.
2. CDC. Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers, *MMWR*, 2015;64:1118–20 at www.cdc.gov/mmwr/pdf/wk/mm6439.pdf.

For additional detailed information about text that you might incorporate into newborn admission orders, including orders for premature infants, refer to *Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission* available at www.immunize.org/catg.d/p2130.pdf.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

U.S. Department of Health and Human Services
Office of the Secretary

THE PRIVACY RULE
45 CFR Parts 160 and 164

Related Excerpts from the Final Regulation Text
Amended as of August 14, 2002

§ 160.102 APPLICABILITY

- (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:
- (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.

§ 164.504 USES AND DISCLOSURES: ORGANIZATIONAL REQUIREMENTS

- (b) **Standard: health care component.** If a covered entity is a hybrid entity, the requirements of this subpart, other than the requirements of this section, apply only to the health care component(s) of the entity, as specified in this section.
- (g) **Standard: requirements for a covered entity with multiple covered functions [or hybrid entity]**
- (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.
 - (2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity’s health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

<p>Does HIPAA apply to public health? HIPAA applies to <i>any</i> entity that performs certain covered functions (the performance of which would by definition make the entity a health plan, health care provider, or health information clearinghouse). Any part of a public health system that answers affirmative to all of the following questions may be subject to HIPAA and its requirements.</p>		
<p>(1) Does the entity (in whole or in part) perform any of the following covered functions...?</p>	<ul style="list-style-type: none"> • provide [for] or pay the cost of medical care; • provide [direct] medical or health services (or furnish, bill, or receive payment for health care in the normal course of business); or • receive, process, or facilitate the processing of health information received from another entity into standard or nonstandard formats. 	
<p>(2) Does the entity receive or transmit individually identifiable health information pertaining to...?</p>	<ul style="list-style-type: none"> • health plan enrollment (or disenrollment); • health plan eligibility determinations; 	<ul style="list-style-type: none"> • claim submissions (encounter info); • health plan benefit coordination; • claim status inquiries;
<p>(3) Does the entity conduct any or all of these standard transactions electronically...?</p>	<ul style="list-style-type: none"> • health plan premium payments; • referral certification, authorization; 	<ul style="list-style-type: none"> • payment and remittance advices; • first report of injury; and/or • health claim attachments.

This document contains selected text from the HIPAA Privacy Rule [45 CFR Parts 160 and 164]. It is not a complete analysis nor is it legally binding. Covered entities are advised to seek legal counsel for answers to legal questions.

§ 164.512(b) STANDARD: USES AND DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

- (1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:
 - (i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;
 - (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 Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:
 - (A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;
 - (B) To track FDA-regulated products;
 - (C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or
 - (D) To conduct post marketing surveillance;
 - (iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or
 - (v) An employer, about an individual who is a member of the workforce of the employer, if:
 - (A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:
 - (1) To conduct an evaluation relating to medical surveillance of the workplace; or
 - (2) To evaluate whether the individual has a work-related illness or injury;
 - (B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
 - (C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
 - (D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:
 - (1) By giving a copy of the notice to the individual at the time the health care is provided; or
 - (2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.
- (2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

§ 164.506 USES AND DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS

- (a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.
- (c) *Implementation specifications: Treatment, payment, or health care operations.*
- (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.
 - (2) A covered entity may disclose protected health information for treatment activities of a health care provider.
 - (3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.
 - (4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:
 - (i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or
 - (ii) For the purpose of health care fraud and abuse detection or compliance.
 - (5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

§ 164.512(a) USES AND DISCLOSURES REQUIRED BY LAW

- (1) A covered entity may use or disclose protected health information 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.
- (2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

§ 164.512(d) USES AND DISCLOSURES FOR HEALTH OVERSIGHT ACTIVITIES

- (1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
 - (i) The health care system;
 - (ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
 - (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
 - (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

§ 164.512(d) USES AND DISCLOSURES FOR HEALTH OVERSIGHT ACTIVITIES (cont'd)

- (2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:
- (i) The receipt of health care;
 - (ii) A claim for public benefits related to health; or
 - (iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
- (3) *Joint activities or investigations.* Notwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.
- (4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

The Public Health Exception

HIPAA expressly permits covered entities to disclose protected health information for the following purposes:

EXCEPTIONS—A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law—

- (A) is a provision the Secretary determines—
 - (i) is necessary—
 - (I) to prevent fraud and abuse;
 - (II) to ensure appropriate State regulation of insurance and health plans;
 - (III) for State reporting on health care delivery or costs; or
 - (IV) for other purposes; or
 - (ii) addresses controlled substances; or
- (B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

PUBLIC HEALTH—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

STATE REGULATORY REPORTING—Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

Source: Public Law 191, 110 Stat. 2030, 104th Congress, 2nd Session (21 August 1996), *Health Insurance Portability and Accountability Act*.

§ 164.512(j) USES AND DISCLOSURES TO AVERT A SERIOUS THREAT TO HEALTH OR SAFETY

- (1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or 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 or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
 - (ii) Is necessary for law enforcement authorities to identify or apprehend an individual:
 - (A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or
 - (B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.
- (2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:
 - (i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or
 - (ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.
- (3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.
- (4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

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DEFINITIONS

Business associate^{*}:

- (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:
 - (i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:
 - (A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or
 - (B) Any other function or activity regulated by this subchapter; or
 - (ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.
- (2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.
- (3) A covered entity may be a business associate of another covered entity.

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.

Covered functions[†] means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Direct treatment relationship[†] means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Disclosure[†] means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

Health care clearinghouse^{*} means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions:

- (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.
- (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care component[†] means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with paragraph (c)(3)(iii) of this section.

Health care provider^{*} means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information^{*} means any information, whether oral or recorded in any form or 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.

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 an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, 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.

Health plan^{*} means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

- (1) *Health plan* includes the following, singly or in combination:
 - (i) A group health plan, as defined in this section.
 - (ii) A health insurance issuer, as defined in this section.
 - (iii) An HMO, as defined in this section.
 - (iv) Part A or Part B of the Medicare program under title XVIII of the Act.
 - (v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.
 - (vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).
 - (vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.
 - (viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.
 - (ix) The health care program for active military personnel under title 10 of the United States Code.
 - (x) The veterans health care program under 38 U.S.C. chapter 17.
 - (xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)(as defined in 10 U.S.C. 1072(4)).
 - (xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.
 - (xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.
 - (xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.
 - (xv) The Medicare + Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.
 - (xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.
 - (xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) *Health plan* excludes:

- (i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and
- (ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):
 - (A) Whose principal purpose is other than providing, or paying the cost of, health care; or
 - (B) Whose principal activity is:
 - (1) The direct provision of health care to persons; or
 - (2) The making of grants to fund the direct provision of health care to persons.

Hybrid entity[†] means a single legal entity:

- (1) That is a covered entity;
- (2) Whose business activities include both covered and non-covered functions; and
- (3) That designates health care components in accordance with paragraph (c)(3)(iii) of this section.

Indirect treatment relationship[†] means a relationship between an individual and a health care provider in which:

- (1) The health care provider delivers health care to the individual based on the orders of another health care provider; and
- (2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

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.

Plan administration functions[†] means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Protected health information[†] means individually identifiable health information:

- (1) Except as provided in paragraph (2) of this definition, that is:
 - (i) Transmitted by electronic media;
 - (ii) Maintained in any medium described in the definition of *electronic media* at § 162.103 of this subchapter; or
 - (iii) Transmitted or maintained in any other form or medium.
- (2) *Protected health information* excludes individually identifiable health information in:
 - (i) Education records covered by the Family Educational Rights and Privacy Act,
 - (ii) as amended, 20 U.S.C. 1232g;
 - (iii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and
 - (iv) Employment records held by a covered entity in its role as employer.

* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

Public health authority[†] means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research[†] means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Required by law[†] means a mandate contained in law that compels an 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.

Trading partner agreement^{*} means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

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.

Use[†] means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

This document contains selected text from the HIPAA Privacy Rule [45 CFR Parts 160 and 164]. It is not a complete analysis nor is it legally binding. Covered entities are advised to seek legal counsel for answers to legal questions.

* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

Department of State Health Services

Notice of Privacy Practices

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.

Si quiere este aviso en español, llame gratis al 2-1-1 o al 1-877-541-7905.

About this Notice:

Effective date: This Notice takes effect on July 20, 2015 and stays in effect until replaced by another notice.

This Notice is required by HIPAA (the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §1320d, et seq., and regulations adopted under that act).

In this Notice, “agency,” refers to the Texas Department of State Health Services.

This Notice tells you about: (1) your privacy rights, (2) the agency’s duty to protect health information that identifies you, and (3) how the agency can use or share health information that identifies you without your written permission. This Notice doesn’t apply to health information that does not identify you or your legally authorized representative.

In this Notice, “You” or “your” means you, the individual to whom this Notice is addressed or your legally authorized representative.

In this Notice, “health information” means:

- Medical information or legally protected health information about you whether in oral, paper or electronic form that relates to:
 - Your past, present, or future physical or mental health or condition;
 - Health care provided to you; or
 - The past, present, or future payment for providing your health care.
- Genetic information about you, and
- Health Information created or received by a health-care service provider, health plan, public health authority, employer, life insurer, school or university, or health-care clearinghouse.

The agency reserves the right to change the terms of this Notice. The new Notice will be sent to your most recent address that the agency has on file. It is your duty to promptly tell the agency if you have had a change of address. The practices in the new Notice will apply to all the health information the agency has about you, regardless of when the agency received or created the information.

The agency is considered a “hybrid covered entity,” which means that only certain parts of the agency have health care components and others are not. This Notice applies to the parts of the agency that are health care components, or are serving as a health care provider (for example, agency state mental health hospitals and the agency Laboratory), health plan services known as “Texas Health Steps” and the agency’s Centralizing Billing Services health care clearinghouse.

Your privacy rights:

The law gives you the right to:

- Receive adequate notice of: (1) the uses and disclosures of protected health information that can be made by the agency or your health-care service provider, (2) your rights related to your health information, and (3) the agency's and health-care service provider's legal duties to protected health information, with some legal exceptions. The agency provides you this notice via this Notice of Privacy Practices, which is also available online on the agency's website: www.dshs.state.tx.us.
- Ask the agency or your health-care service provider to restrict certain uses or disclosures of health information about you. The agency is not required to agree to these requests, except in some cases when you request that we not disclose information to your health plan about services for which you paid with your own money in full. The agency may require your request to be in writing.
- Request confidential communications about your health information and make reasonable requests to get information in a different way or location. The agency or health-care service provider may require the request to be in writing with a statement or explanation for the request. For example, you might explain that sending information to your usual address might put you in danger. You must be specific about where and how the agency can contact you.
- In some situations, look at or get a copy of certain health information, including laboratory test results that the agency or your health-care service provider has about you.
- Ask the agency or your health-care service provider's privacy office to correct certain information about you if you believe the information is wrong or incomplete. Most of the time, the agency can't change or delete information, even if it is incorrect. If the agency or health-care service provider decides it should make a correction, it will add the correct information to the record and note that the new information takes the place of the old information. The old information will remain in the record. If the agency or health-care service provider denies your request to change the information, you can have your written disagreement reviewed by the agency's privacy officer and placed in your record.
- Ask for a list of disclosures the agency or health-care service provider has made of certain health information.
- Ask for and get a paper copy of this Notice from the agency or its privacy office.
- Cancel permission you have given the agency or your health-care service provider to use or share health information that identifies you in some cases, unless the agency or health-care service provider has already taken action based on your permission. You must cancel your permission in writing and deliver it to the agency's privacy office.
- In some situations, be notified by letter from the agency's privacy officer if your health information has been used or shared in an unauthorized manner.
- Be notified of material changes to the way the agency uses or shares health information about you. All changes to the Notice will be posted on the agency's web site and the revised Notice will be available to you at your health provider's office.
- For all notices to, or requests for copies of information from, the agency or health-care service provider's privacy office, please see the "Complaints and Questions" section for contact information.

The agency's duty to protect health information that identifies you:

The law requires the agency to take reasonable steps to protect the privacy and security of your health information. It also requires the agency to give you this Notice, which describes the agency's legal duties and privacy practices. In most situations, the agency can't use or share health information that identifies you without your written authorization, except to carry out treatment, payment for your health care or the agency's health-care operations, or as required by law, as described below. This Notice explains under

what circumstances the agency can use or share health information that identifies you without your permission. The agency is required to abide by the terms of the notice currently in effect.

Agency workforce (employees, trainees, volunteers and staff augmentation contractors) are trained and required to protect your health information. The agency does not give employees access to health information unless they need it for a business reason. Business reasons for needing access to health information include but are not limited to making benefit decisions, paying bills and planning for the care you need. The agency will punish employees who do not protect the privacy of health information that identifies you, according to law and agency policy.

The agency will notify you if your unsecured protected health information is breached, as required by law. The agency is required to notify you even if there is no reason to suspect any misuse of the protected health information. You will be notified by mail or by phone as soon as reasonably possible. It is your duty, or the duty of your legally authorized individual, to promptly tell the agency if you have had a change of address.

Uses and disclosures that might require your written authorization:

Agency uses or disclosures that might require your authorization include but are not limited to the following:

1. Psychotherapy notes. The agency must get your authorization, in some cases, to disclose your psychotherapy notes (certain notes that are taken by your mental health professional during the course of a counseling session) except:

- To carry out treatment, payment, health-care operations, or as required by law,
- For use by the originator of the psychotherapy notes for treatment,
- For use by the agency for its own training programs, or
- For use by the agency to defend itself in a legal action or other proceedings brought by you or your legally authorized representative.

2. Marketing. If applicable, the agency will not use or share your health information without your authorization for marketing communications about a product, such as a drug or medical device, or services that encourage you to buy or use a product or service, except if the communication is in the form of:

- A face-to-face communication made by the agency to you, or
- A promotional gift of little value provided by the agency.

If the marketing involves direct or indirect payment to the agency from a third party, the authorization must state that such payment is involved. The following activities are not considered marketing and don't require your authorization:

- Refill reminders or other communications about a drug or biologic that is currently being prescribed for you, as long as any payment received by the agency in exchange for the communication is reasonably related to the agency's cost of the communication.
- Certain treatment and health-care operation activities, except where the agency gets payment in exchange for making the communication:

3. Sale of Protected Health Information. The agency will not sell your protected health information to any other person in exchange for direct or indirect payment, except:

- To another health care provider, health plan or healthcare clearinghouse for treatment, payment, or health care operations; or
- To perform an insurance or health maintenance organization function authorized by law; or
- As otherwise authorized or required by state or federal law.

“Sell” or a “sale” means disclosures by the agency or its business associate where there is a direct or indirect payment from or on behalf of the third-party that gets the protected health information in exchange for payment.

- 4. Fundraising.** If applicable, the agency must get your written authorization if it shares your protected health information for fundraising purposes, except the agency may use or share the following health information with a business associate or to an institutionally related foundation:
- Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth; and
 - Dates of health care provided to an individual;
 - Department of service information;
 - Treating physician;
 - Health outcome information; and
 - Health insurance information.

For example, the agency might participate in fundraising activities, organized by its state mental hospitals' volunteer services councils that are designed to improve the quality of patient care. These volunteer services council fundraising events are strictly voluntary and might include art shows, walks, runs, or bike rides. You must first provide the agency with your written authorization for any instance in which you choose to share your protected health information for such fundraising purposes.

- 5. Genetic information.** The agency will never use genetic information for underwriting purposes.

Uses and disclosures that do not require your written authorization:

- 1. Treatment.** The agency can use or share your health information with other health-care providers involved with your treatment. For example, the agency may provide your information to other providers so you can be seen by a specialist health-care provider for a consult. Or, if you are in a hospital, you may be treated by multiple health-care providers who have your information. By getting your information, health-care service providers will better understand your health history, which could help them provide your health care.
- 2. Payment.** The agency can use or disclose certain health information about you to pay or collect payment for your health care. For example, when your health-care service provider sends a bill to the agency or your health plan, it includes certain information about your condition and treatment. Another example would be when the agency uses or discloses your health information to determine either your eligibility for government benefits in a health plan, or whether the proposed treatment is covered by your insurance.
- 3. Health-care operations.** The agency can use or share health information about you for its health-care operations. The agency's health-care operations include but are not limited to:
 - Conducting quality assessment and improvement activities,
 - Reviewing the competence, qualifications, and performance of health-care professionals or health plans,
 - Training health-care professionals and others,
 - Conducting accreditation, certification, licensing, or credentialing activities,
 - Carrying out activities related to the creation, renewal, or replacement of a contract for health insurance or health benefits,
 - Providing, receiving or arranging for medical review, legal services, or auditing functions, and
 - Engaging in business management or the general administrative activities of the agency.

The agency can also share health information about you with the agency's business associates (contractors) or business associate's subcontractors, if the business associate or the subcontractor:

- Needs the information to perform services on behalf of the agency, and
- Agrees to protect the privacy of the information according to agency standards.

Other examples of uses and disclosures for health-care operations by the agency include but are not limited to using or disclosing health information for case management; ensuring the agency's health-care service provider is qualified to treat individuals; or auditing a health-care service provider's bill to ensure the agency has been billed for only care you received. The agency also can contact you to tell you about treatment alternatives or additional benefits you might be interested in.

4. Government Health Benefits. If you apply for or enroll in government health benefits provided by the agency, such as Medicaid benefits, the agency can use or share health information about you in order to:

- Establish your eligibility for health benefits;
- Determine the amount of Medical Assistance to be provided to you;
- Provide health services to you; and
- Conduct or assist with an investigation, prosecution, or civil or criminal proceeding related to your health benefits.

5. Family members, other relatives, guardians, legally authorized representatives (LAR) or close personal friends. The agency can share your health information, with your agreement, or in an emergency if you are incapable of agreeing, or as otherwise authorized by law, with a family member, other relative, guardian, legal authorized representative, or close personal friend:

- When directly relevant to such person's involvement with your health care or payment related to your health care; or
- To notify the person of your location, general condition, or death.

Your "family" or "relative" means:

- (1) Your dependent, or
- (2) Any other person who is your first-degree, second-degree, third-degree, or fourth-degree relative, such as your:
 - Parents, spouses, siblings, and children.
 - Grandparents, grandchildren, aunts, uncles, nephews, and nieces.
 - Great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.
 - Great-great grandparents, great-great grandchildren, and children of first cousins.

The agency can make reasonable inferences of your best interest in allowing a person to act on your behalf such as to pick up prescriptions, medical supplies, X-rays, or other similar forms of protected health information, unless disclosure of the information is prohibited by law, such as substance use disorder information.

6. Substance Use Disorder Program Information. The agency is prohibited by law from sharing substance use disorder information about you or information that identifies you as seeking or getting substance use disorder treatment from a substance use disorder provider, program or facility to anyone, including family members, relatives, or friends without your written permission, unless permitted by law, for example in a medical emergency.

7. Mental Health Information. The agency will not share information about your mental health (information about your identity, diagnosis, evaluation, or treatment that are created or maintained by a professional for diagnosis, evaluation, or treatment of any mental or emotional condition or disorder, including alcoholism or drug addiction), unless expressly authorized by law.

8. "Required by law" uses or disclosures of PHI. The agency may use or disclose your protected health information 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, for example:

- A. To Government programs providing public benefits.** When administering a program providing public benefits, the agency may disclose protected health information relating to the program to another HIPAA-covered entity that is a government agency administering a government program providing public benefits if:
- The programs serve the same or similar types of people, and
 - The disclosure of protected health information is necessary to coordinate or improve how the programs are run.
- B. For Health oversight activities.** The agency might use or share health information about you to a health oversight agency for health oversight activities authorized by law. A health oversight agency must be a government agency or someone acting on behalf of a government agency.
- C. For Public health activities.** The agency can share health information about you as required by law for public health purposes, such as to:
- A public health authority for purposes of preventing or controlling disease, injury, or disability.
 - An official of a foreign government agency who is acting with the public health authority, and
 - A government agency allowed to get reports of child abuse or neglect.
- D. Victims of abuse, neglect or domestic violence.** The agency may disclose protected health information about you if the agency reasonably believes you 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, to the extent the disclosure is required by law and the disclosure complies with and is limited to what the law allows if:
- You agree to the disclosure;
 - A law authorizes disclosure; and
 - The agency, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to you or others, or
 - If you are unable to agree because you are incapacitated, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against you and is needed for immediate action.

If the agency makes a report under this section, the agency will tell you or your legally authorized representative about the report unless:

- The agency in good faith believes that telling you would place you at risk of harm; or
 - The agency reasonably believes your legally authorized representative may be responsible for the abuse and telling that person would not be in your best interests.
- E. Serious threat to health or safety.** The agency can use or share health information about you if it believes the use or disclosure is needed:
- To prevent or lessen a serious and immediate threat to the health and safety of a person or the public and the disclosure is made to a person reasonably able to lessen or prevent such a threat;
 - For law enforcement authorities to identify or catch an individual who has admitted participating in a violent crime that resulted in serious physical harm to the victim, unless the information was learned while initiating or in the course of counseling or therapy; or
 - For law enforcement authorities to catch an individual who has escaped from lawful custody.
- F. For other law enforcement purposes.** The agency can share health information about you to a law enforcement official for the following law enforcement purposes:
- To comply with certain legal reporting requirements;

- To comply with a grand jury subpoena;
- To comply with an administrative request, such as a civil investigative demand that is specific and limited in scope, if the information is relevant to a legitimate law enforcement inquiry and de-identified information cannot reasonably be used;
- To identify and locate a suspect, fugitive, witness, or missing person, as long as the information provided to law enforcement is specifically authorized by law;
- In response to a request for information about an actual or suspected crime victim, if either:
 - The individual agrees to the disclosure; or
 - The requesting law enforcement official represents that the information is not intended to be used against the victim, is needed to determine whether a violation of law has occurred, and the agency determines that disclosure is in the best interests of the individual;
- To alert a law enforcement official of a death that the agency suspects is the result of criminal conduct; or
- To report evidence of a crime on the agency's property.

- G. For judicial or administrative proceedings.** The agency may share your health information in the course of any judicial or administrative proceeding with:
- A court order to share your health information from a regular or administrative court;
 - A subpoena or request by a party to a lawsuit that the agency is also a party to, except a court order is required to disclose substance use disorder information, and the agency may ask the court for a protective court order.
 - In some situations, you or your legally authorized representative will be notified of the request for your health information in the proceeding.

- H. To the Secretary of U.S. Department of Health and Human Services.** The agency must share health information about you to the Secretary of U.S. Department of Health and Human Services for legal compliance purposes.

- I. Research.** The agency can use or share health information about you for research:
- If certain information about you is removed so that it is de-identified,
 - If you authorize the research,
 - If the research is approved by an Institutional Review Board or Privacy Board, or
 - As otherwise authorized by law

Your health information also can be used:

- To allow a researcher to prepare a research protocol, as long as the researcher
 - demonstrates that this information is necessary for the research
 - does not remove the information from the agency, or
 - agrees to keep the information confidential, or
- To allow a researcher to obtain information about people who have died, as long as the researcher
 - represents that the information is necessary for research that involves information about people who have died, and
 - provides, when requested, evidence of the death of the person whose information is sought

- J. Correctional institutions and other law enforcement custodial situations.** The agency may disclose an individual's health information to a correctional institution or law enforcement official that has lawful custody of that individual, as long as the institution or official tells the agency that the information is necessary:
- To provide that individual with health care;
 - To protect the health or safety of that individual or others related to the activities of the correctional institution; or
 - As otherwise required by law.

K. Other uses and disclosures. The agency can otherwise use or share health information about you:

- To create information that is de-identified and doesn't identify you.
- For military or veteran activities as required by law.
- For purposes of lawful national security activities.
- To federal officials to protect the president of the United States and others.
- To comply with workers' compensation laws or similar laws.
- To tell coroners or funeral directors about your death as required by law.
- As otherwise required or permitted by local, state or federal law.

Complaints and questions about the use or disclosure of your information:

If you believe your privacy rights have been violated, contact the agency. You may contact the agency if you: (1) have questions about this notice, (2) need more information about your privacy rights, (3) need a physical address for the agency, or (4) are requesting a copy of health information from the agency:

- **Texas Department of State Health Services (DSHS):** Call 1-512-776-7111 or 1-888-963-7111 (toll free) or email hipaa.privacy@dshs.state.tx.us.
- To request your results of lab tests performed by the DSHS Laboratory, please call (512) 776-7318 or visit <http://www.dshs.state.tx.us/lab/patientresults.aspx>.
- If you are receiving care from a DSHS state-operated hospital, contact the hospital's privacy office, or
- You may also contact: **DSHS Consumer Services and Rights Protection/Ombudsman Office** by mail at Mail Code 2019, P.O. Box 149347 Austin, TX 78714-9347; or by telephone at (512) 206-5760 or (800) 252-8154 (toll free).

If you believe the agency has violated your privacy rights, you also can file a complaint with the:

Secretary
Office of Civil Rights
Region VI
U.S. Department of Health and Human Services
1301 Young St., Suite 1169
Dallas, Texas, 75202
Voice Phone (800) 368-1019
FAX (214) 767-0432
TDD (800) 537-7697

For complaints about a violation of your right to confidentiality by an alcohol or drug abuse treatment program, contact the United States Attorney's Office for the judicial district in which the violation occurred.

The agency prohibits retaliation against you for filing a complaint.

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