



231322

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111
<http://www.tdh.state.tx.us>

TEXAS BOARD OF HEALTH

Walter D. Wilkerson, Jr., M.D., Chairman
Mary E. Ceverha, M.P.A., Vice-Chair
Mario R. Anzaldúa, M.D.
J. C. Chambers
Beverly H. Robinson, Ph.D., R.N., C
Margo S. Scholin, J.D.

February 15, 2000

US Department of Health and Human Services
Assistant Secretary for Planning and Evaluation
Attn: Privacy-P Room G-322a
Hubert H. Humphry Building
200 Independence Avenue SW
Washington, DC 20201

RE Standards for Privacy of Individually Identifiable Health Information

Dear Assistant Secretary

The Texas Department of Health (TDH) has reviewed the standards for privacy of individually identifiable health information which were published in the Federal Register on November 3, 1999. TDH will be affected by the regulations because it is a covered entity in part. Covered entities within TDH include TDH's public health laboratory, two TDH hospitals, TDH public health clinics, the acute care portion of the state's Medicaid program, and a portion of the state's children's health insurance program. TDH also receives health information, individually identifiable and de-identified, from covered entities. The information is received in the above-referenced programs as well as other TDH programs, such as those which handle birth and death records, immunization registry, licensing of professionals and facilities, epidemiology, newborn screening, communicable disease reporting, and personnel/insurance. The use and disclosure of protected health information is frequently a critical element for TDH to carry out its mission to protect public health. Protection of an individual's privacy is also crucial. However, each requirement established to protect privacy should be balanced against any substantial burden or costs of compliance placed upon public health functions.

The following are comments on the proposed regulations

Concerning the definition of "health plan" in Section 160.103, what will constitute an individual plan that provides, or pays the cost of, medical care? TDH administers a number of programs that pay the cost of medical care for individuals within the State of Texas. In some cases TDH pays the cost of medical care directly to an individual's health care provider and in other cases TDH gives a grant to an organization, such as a local (city or county) health department, which then provides medical care or pays the cost of medical care for an individual. For example, TDH's Children with Special Health Care Needs Program accepts certain applicants needing financial assistance for the cost of

medical care. TDH contracts with health care providers for that care. The providers file claims for payment. TDH pays those claims under this program. The program is established pursuant to a state law expressly governing this program. Does the Children with Special Health Care Needs Program qualify as a “health plan”? A second example is TDH’s HIV Medication Program. This program assists HIV-positive individuals. TDH provides medications and pays a service fee to pharmacies which provide the medications without further charge to the HIV-positive individuals. Does this program constitute a “health plan”? A third example is the Kidney Health Care Program which covers some costs of dialysis or kidney transplantation. The program pays claims for medical care submitted by approved providers or by the individual who has made a direct payment to a provider for services. Is this a “health plan”? A fourth example is the Tuberculosis Program. Generally TDH contracts with a local health department to provide funds to the local health department, and the local health department then provides tuberculosis services to individuals utilizing at least in part the funds provided by TDH. Is this a “health plan”?

Concerning the definition of “health plan” in Section 160.103, the definition states that the term “health plan” includes, “when applied to government funded or assisted programs, the components of the government agency administering the program.” If all of the above programs are “health plans”, this language seems redundant since the TDH programs are actually “individual plans” under the definition. TDH requests that further explanation of this portion of the definition be provided.

Concerning the definition of “health care provider” in Section 160.103, TDH’s contractors under the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) provide immunizations to eligible WIC clients and forward this protected health information to TDH. Are WIC clinics “health care providers”?

Concerning the definition of “health care clearinghouse” in Section 160.103, TDH reads the definition as not applicable to the processing of nonstandard data elements into standard elements when the transaction is not forwarded to appropriate payers or clearinghouses. For example, TDH’s central billing system (CBS) is a computerized database containing client demographic information and eligibility dates for Medicaid and Medicare services. CBS receives protected health information from TDH’s public health laboratory (a health care provider) and health care providers (mainly TDH and local health department clinics). CBS matches the protected health information with its database and forwards a claim (bill) to the Medicaid program, if appropriate, for payment. Because some of the clinics are not TDH owned or operated, CBS appears to be a health care clearinghouse. If CBS only forwarded claims from TDH owned or operated clinics to the Medicaid program, also within TDH, it would not constitute a clearinghouse since the information is not from or forwarded to an entity outside of TDH. Is this correct?

In addition CBS forwards protected health information on pregnant women to TDH’s WIC program which may contact the women to determine their eligibility for WIC services. If this were CBS’ only function, is TDH’s understanding correct that CBS would not be a clearinghouse since it would not be sending the information to a payer or clearinghouse?

Concerning the definition of “health care provider” in Section 160.103, would medical case management constitute the provision of services under this definition? Case management is a means

of assisting eligible recipients in gaining access to medically necessary and appropriate medical, social, educational, and other services. Would a program which refers individuals to appropriate medical or health care be considered to be a covered entity?

Concerning the definition of “covered entity” in Section 160.103, TDH requests that the definition be clarified to articulate that when a covered entity is a part of a larger organization, the regulations apply only to the covered entity that is a component of the organization that itself is not a covered entity. This is stated in the preamble but not in the regulations. Is TDH’s understanding correct that even though certain programs within TDH may come within the definition of “covered entity”, the rest of TDH will not be treated as a covered entity?

Concerning Section 160.204(a) relating to exceptions from the general rule of preemption of state law, certain exceptions require approval from the Secretary of the Department of Health and Human Services (DHHS) while other exceptions allow a provision of state law to govern without express approval of the secretary TDH requests that the approval process for the secretary be deleted and that states be authorized to apply state law when one of the conditions articulated in Section 160.203 is found by the state to exist. Documentation of the determination could be required and compliance verified by DHHS under Section 164.522. Since states can determine exceptions under Section 160.203(b)-(d), there is insufficient justification for the additional administrative burden of submitting requests to DHHS to determine exceptions under Section 160.203(a).

In the alternative if the secretary’s approval remains, a time period for making such a determination should be included. If the secretary fails to make a written determination within that time period, the state’s determination of the application of state law should be recognized in the rules. In addition in order to promote efficiency of government, any exception granted should be effective indefinitely (or as long as the state law remains unchanged) until a new exception is granted or denied.

Concerning Section 164.104 on applicability of the regulations to covered entities, TDH requests that the final regulations continue to only be applicable to the use or disclosure by a covered entity of an individual’s protected health information that is or has been electronically transmitted or electronically maintained. TDH requests that the coverage of these regulations not be broadened at this time. The regulations sufficiently implement the pertinent portions of the Health Insurance Portability and Accountability Act of 1996.

Concerning Section 164.506(f) relating to uses and disclosures of protected health information of deceased individuals, a deceased individual has no constitutional right to privacy; however, most states have state laws relating to the confidentiality of medical information. The State of Texas has enacted the Medical Practice Act which makes medical records confidential and allows release, whether the individual is alive or deceased, only under certain circumstances. TDH would suggest that state laws are sufficient to maintain protections for protected health information of deceased individuals and that this standard in the proposed regulations should be deleted. In addition many covered entities holding protected health information will not know when an individual becomes deceased but will continue to treat the protected health information under these regulations.

Concerning Section 164.506 relating to uses and disclosures of protected health information: general

rules, TDH suggests that all of Subsection (c) relating of the right to the individual to restrict uses and disclosures be deleted. A covered entity (in this section a health care provider) is not required to agree to any requested restriction. Since use and disclosure is only required if an individual requests access to his or her own protected health information or when DHHS requests access to the information for the purpose of enforcement of the regulations, it appears that a covered entity could, even without the subsection, agree to other restrictions. It is not necessary to establish a standard to that effect or to require a covered entity to develop additional procedures for an activity that is discretionary on the part of the covered entity. The additional burden on the covered entity outweighs the benefit to the individual of articulating and enforcing this discretionary process.

Concerning Section 164.506(d)(2)(ii)(A) relating to use or disclosure of deidentified protected health information, driver's license number should be added to the list as an identifier to be removed or concealed. While a driver's license number may be considered to be within the language of subclause (19), current litigation concerning the confidentiality of these numbers in Texas indicates that confidentiality should be clearly articulated in statutes and rules whenever possible.

Concerning Section 164.506(d)(2)(iii) relating to use or disclosure of deidentified information, it is important that entities with the described experience and expertise be able to determine what constitutes deidentifiable information. This subparagraph should be kept in the final regulations.

Concerning Section 164.506(e) relating to standards for business partners, the term "business partner" is defined in Section 164.504. The definition covers a person to whom the covered entity discloses protected health information so that the person can carry out, assist, or perform a function or activity for the covered entity. The definition does not cover a person from whom the covered entity receives protected health information under a contractual relationship whereby the person carries out, assists, or performs a function or activity for the covered entity. For example, a health care provider may provide protected health information directly to a person who has contracted with TDH to provide certain functions for TDH. Because the person is not receiving protected health information from TDH, the person is not within the definition of "business partner". There may instances where the person qualifies on its own as a health care clearinghouse, health plan, or health care provider; however, is it correct that the person described in the example would be excluded from the definition of "business partner"?

A second example involves TDH contracting pursuant to express state statutory authority with a health care provider, such as a physician. The physician provides medical services to a client and sends protected health information to TDH, such as claims for payment. TDH performs certain activities or functions to pay the physician/contractor, but TDH is not performing those activities or functions "for the covered entity". Is TDH correct that this arrangement would not make TDH a business partner of the physician?

A third example involves a health care provider, such as a hospital, which submits protected health information to TDH's office which issues birth certificates. This step is within the exceptions to the proposed regulations found in Section 160.203(c). However, this TDH office also assists the state Medicaid offices to see that the newborn identified in the birth certificate is enrolled in the Medicaid program if eligible. The Medicaid enrollment is then conveyed back to the hospital. Is TDH correct

that these facts would not make TDH's birth certificate office a business partner of the hospital since TDH is performing a function of the Medicaid program, enrollment, rather than an activity "for" the hospital?

Concerning Section 164.508(a)(1) and (c) relating to uses and disclosures for which individual authorization is required, if an individual's request would fit within one of the uses or disclosures articulated in Section 164.510 for which individual authorization is not required, is the individual still required to sign an authorization or may the covered entity simply recognize that the use or disclosure requested is allowed under Section 164.510?

Concerning Section 164.512 relating to notice to individuals of information practices, the requirement implicit in this section is a notice individualized for a named individual. To require individualized notices from a large public health agency such as TDH would create an extremely costly task for the agency. TDH has over 100 programs, many of which are or may be covered entities. TDH holds protected health information in many of these programs but does not have a centralized filing system for the protected health information held by these programs. Considering that TDH may hold protected health information on thousands of individuals who have received services within the State of Texas over a number of years, an individualized notice would be a tremendous burden. TDH requests that covered entities be permitted to issue general statements of use and disclosure, rather than individualized notices. In the alternative, TDH requests that governmental agencies be exempt from Section 164.512 or at least that governmental agencies be exempt if the agency is not providing face to face services to the individual. If general statements are not permissible or no exemption is created, the notice requirements should be amended to require notice only of protected health information in designated record sets since such information can more easily be identified by the covered entity. In addition the notice should be provided at the time of enrollment, not periodically after that time, unless the contents of the notice change. Clients are often confused by the paperwork which they receive and further stress on those clients can be avoided by only providing the notice once.

Concerning Section 164.514 relating to access of individuals to protected health information, TDH requests that this section be amended to allow a state's law on open records or freedom of information from governmental agencies to govern when the covered entity is a governmental agency.

Concerning Section 164.515 relating to accounting for disclosures of protected health information, TDH suggests that this entire section be deleted because of the unreasonable burden it places on covered entities. In the alternative, any governmental agencies which are covered entities should be exempt from the accounting requirement. Government agencies are most likely to have received or disclosed the information for the very reasons state in subsection (a)(1) or (2). Because of the large amount of protected health information that a governmental agency may hold relating to individuals, this section places an unreasonable burden upon those agencies.

If Section 164.515 is kept, Subsection (a)(2) should be revised to delete the requirements for a written request from the health oversight or law enforcement agency. This requirement places an additional burden upon these agencies which are not generally covered entities or subject to other express requirements of these regulations. The requirement also places an unreasonable burden on

covered entities to track the written request from the agency

As your agency addresses the many comments received on these proposed regulations, TDH asks that you balance the protection of the privacy of individuals with the necessity of additional costly requirements which may harm the ability of public health agencies to carry out their extensive activities aimed at protecting the health and safety of those same individuals.

Thank you for your consideration of these comments. If you have any comments, please feel free to contact Linda Wiegman, Supervising Attorney in TDH's Office of General Counsel at (5 12) 458-7236.

Sincerely,

A handwritten signature in black ink, appearing to read "William R. Archer III". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

William R. Archer III, M.D.

Commissioner of Health

sks/lw