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I. Introduction

This AIDS Law Brief Background Paper assesses the legal environment of health information privacy laws in Tanzania relevant to HIV/AIDS services and compares Tanzania's existing legal framework with UNAIDS' "Consideration and Guidance for Countries Adopting National Health Identifiers." This AIDS Law Brief Background Paper was prepared by the University of Washington and provides support for an AIDS Law Brief on HIV/AIDS and Health Information Privacy in Tanzania. This Background Paper does not constitute legal advice and should not be relied on for purposes of complying with Tanzanian law.

II. Summary

- The primary laws affecting health information privacy in Tanzania are the Constitution and HIV and AIDS Act
- Tanzania's Constitution establishes a right to privacy in one's own person, family and matrimonial life
- The HIV and AIDS Act states that health practitioners may not breach medical confidentiality or disclose information about a person's HIV or AIDS status, unless an exception applies
- Various national guidelines include health information confidentiality and security provisions

III. Background

Health information privacy laws generally consist of three interrelated categories of protections covering: (1) confidentiality; (2) security; and (3) enforcement. Confidentiality provisions generally govern when personal health information may be disclosed and how it can be used. Security provisions usually require the implementation of technical and procedural safeguards to prevent personal health information from being inadvertently or maliciously accessed by unauthorized individuals. Effective health information privacy frameworks also include enforcement mechanisms, such as patient complaint systems, civil and criminal penalties, and linkages with facility and professional licensing bodies that can conduct regular compliance assessments.

1. Health information privacy protections facilitate the utilization of health services

The problem of confidentiality breaches and HIV stigma in Tanzania is described in Tanzania's 2013 "Multi-Sectoral Framework for HIV and AIDS," which states:

Stigma is highly prevalent in Tanzania at various levels and settings...There is breaching of confidentiality through health delivery systems. While 15% of the PLHIV felt that health care providers did not keep their information confidential, another 5.4% had their serostatus disclosed without their consent. Further, the study revealed discrimination by health care providers. For example, 13% of PLHIV were told not have children, 44% were denied access to reproductive health information, 14% were coerced in accepting

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particular infant feeding options, and about 9% were coerced in their use of family planning methods. Few (19%) eligible pregnant women living with HIV received ART for PMTCT. Others were coerced into sterilization and pregnancy termination by health service providers due to their HIV positive status. The study also reveals high levels of self-stigma.⁵

Confidentiality of health information and the security of personally identifiable health information are particularly important for HIV and AIDS prevention efforts due to high levels of stigma and discrimination surrounding HIV and AIDS.⁶ The impact of HIV stigmatization on health care is an international concern. Treatment seeking behavior is heavily influenced by patients' perceptions of whether or not their information will remain confidential.⁷

Safeguarding privacy and confidentiality are "important for both individuals and society. Individuals are less likely to participate in health research or other socially and individually beneficial activities, including candid and complete disclosures of sensitive information to their physicians, if they do not believe their privacy is being protected." When stigma keeps people from communicating sensitive health information this "in turn affects prevention, care, support, and treatment."

Preserving health information privacy is especially important for the populations most at-risk of contracting HIV, such as injecting drug users, commercial sex workers, and men who have sex with men. For the most at-risk populations, especially, "stigma, discrimination, and criminalization can limit access to care, inhibit service uptake, and reduce patient disclosure of risks." ¹⁰

When effective laws regulating health information privacy are in place, this tends to increase patient trust in how well their personal health information is protected. After the United States passed the new/updated HIPAA Privacy Rule, the public's perception about the confidentiality of their medical records increased. Since HIPAA, "[a] number of studies suggest that the relative strength of privacy, confidentiality, and security protections can play an important role in people's concerns about privacy. As noted, "protecting the privacy of health information is important for ensuring that individuals seek and obtain quality care."

2. Privacy protections are an important component of effective health information management systems

An appropriate legal framework combined with a national health information system — especially one that uses unique patient identifiers — could assist with the process of developing HIV services, promote confidentiality, and strengthen a national healthcare system as a whole. ¹⁴ In order to improve the lives of people living with HIV/AIDS and to reduce HIV transmission, countries must be able "to provide and sustain effective long-term HIV care with ART." ¹⁵

A key element of continuity of care [for HIV patients] is keeping a record which summarizes this care and allows each health worker or counselor to understand what has

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happened before: the patient's HIV clinical stage, weight and functional status; what prophylaxis, other medications, education and psychosocial support have been provided on earlier visits; the patient's family, pregnancy, contraception and TB status (checked at each visit); and a summary of the patient's ART over time. ¹⁶

Keeping such a record requires an effective patient information system that keeps track of demographic information, HIV care and family status, ART data, and patient encounter information.¹⁷

3. Unique patient identifiers facilitate continuity of care, while reducing the chance of inadvertent disclosure

One way to improve the health management information system is the adoption of unique patient identifiers. When adopting unique patient identifiers, it is imperative that the confidentiality and security of patients' personally identifiable information be protected at all levels of the health care system.¹⁸

UNAIDS endorses the use of unique patient identifiers (a.k.a. national health identifiers) to address continuity of care, because it will ensure "that each patient has one unique identity within the health system." If properly implemented, national health identifiers can eliminate "multiple parallel and disconnected patient registration mechanisms." In addition to efficiency, unique health identifiers can be used "to help identify the source of a particular data item without posing any confidentiality risks." However, "[d]eveloping a national patient identification system depends critically on developing the appropriate legal framework to protect patient privacy and corresponding public policy to implement such protections."

IV. Key Findings

Two primary sources embody the legal framework relating to health information privacy in Tanzania. First, Section 16 of the Constitution grants citizens of Tanzania the general right to privacy. Second, the HIV and AIDS (Prevention and Control) Act of 2008 (HIV and AIDS Act) explicitly requires health practitioners to "observe confidentiality in the handling of all medical information and documents."

In addition to these laws, the Ministry of Health and Social Work issued three official guidelines that promote health information privacy: (1) The Standard Operating Procedures for HIV Testing and Counseling, (2) National Guidelines for the Prevention of Mother-to-Child Transmission, and (3) National Guidelines for the Management of the National Aids Control Program.

1. Constitution

The United Republic of Tanzania's Constitution grants citizens a general right to "the privacy of his own person, his family and of his matrimonial life" that includes "respect and protection of his residence and private communications." To protect the right to privacy, "the state authority shall lay down legal procedures regarding the circumstances, manner and extent to which the right to privacy…may be

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encroached upon without prejudice to the provisions of this Article."²⁶ The constitutional right to privacy is not defined in depth, because the Constitution delegates defining the scope of citizens' right to privacy to subsequent legislation.

2. HIV and AIDS Act

The Tanzanian Parliament unanimously passed the HIV and AIDS Act in February 2008.²⁷ The Act prohibits discrimination against HIV-positive people and creates a legal framework for responding to the AIDS epidemic. The Act sets consent-based testing requirements and protects the confidentiality of HIV/AIDS test results specifically, as well as medical confidentiality generally and imposes sanctions for breaching confidentiality.

The HIV and AIDS Act prohibits the unlawful disclosure of "information regarding HIV and AIDS status of any person" and breaches of "medical confidentiality." The confidentiality provisions in the HIV and AIDS Act apply to "[a]ll health practitioners, workers, employers, recruitment agencies, insurance companies, data recorders, sign language interpreters, legal guardians and other custodians of any medical records, files, data or test results." For the purposes of a breach, "all medical information and documents" are considered confidential unless the disclosure falls within a limited set of permissible disclosures. The permissible disclosures apply when:

- (1) complying with monitoring and evaluation requirements,
- (2) informing other health practitioners directly involved or about to be involved in treatment or care of a person living with HIV and AIDS,
- (3) responding to a court order where the main issue is the HIV status of an individual, or
- (4) giving information to a member of the deceased's family.³¹

Outside of these four permissible disclosure purposes, the Act prohibits (a) "breaches [of] medical confidentiality" and (b) unlawful disclosures of "information regarding HIV and AIDS status." Persons convicted of either (a) or (b) are subject to a fine, imprisonment, or both. 33

3. Standard Operating Procedures for HIV Testing and Counselling Services

The Standard Operating Procedures for HIV Testing and Counseling Services ("HTC SOPs") are a general guide for the provision of HTC services at all levels of the health system. "In order to facilitate providers' consistency and conformance to quality standards, best practice and procedures, Standard Operating Procedures (SOPs) have been developed to guide the provision of HTC services at all levels of the health system." The confidentiality provisions discussed in the SOPs apply specifically to staff members and counselors. Three important privacy provisions specifically relate to counseling:

(1) "Disclosure of [HIV test] results to a third person shall only be done with a written consent



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from the person tested."36

- (2) "[C]ounselling will be conducted in private where the conversation between the client and the counsellor cannot be overheard."³⁷
- (3) "Individuals' confidentiality will be protected in conversations between counsellors and other staff members." ³⁸

In addition to the counseling provisions, the HTC SOPs include general comments about confidentiality and security requirements such as "[a]ll clients' information will be kept confidential and private."³⁹ In addition, the HTC SOPs state that client registers and informed consent records "must be managed in accordance with the stipulated standards of confidentiality in the centre. Only persons with a direct role in the management of the client should have access to these records."⁴⁰

The HTC SOPS include a threat of legal action: "Any staff member who breaches confidentiality is acting contrary to the professional code of conduct and may be subjected to legal action." However, the SOPs do not describe who is responsible for enforcing this action. Counselors are required to "sign the oath of confidentiality after being trained. Signing of the oath indicates that the staff member agrees to uphold the confidentiality specific to their work, that all clients' information is confidential and shall not be divulged or made known to unauthorized persons, and that a breach of confidentiality may be grounds for disciplinary action or termination of employment."

4. National Guidelines for the Prevention of Mother-to-Child Transmission of HIV and Keeping Mothers Alive

The National Guidelines for the Prevention of Mother-to-Child Transmission of HIV and Keeping Mothers Alive ("PMTCT Guidelines") were created as a reference for "different stakeholders, including those in research, learning institutions, health facilities, individuals and organisations implementing PMTCT services in the country." The PMTCT Guidelines include a number of confidentiality and security provisions. The PMTCT Guidelines generally state that "[a]ll HCWs and supporting staff at the healthcare facility are responsible for maintaining confidentiality and all should receive training about procedures to carry out this responsibility." In addition, the PMTCT Guidelines include the following confidentiality and security provisions:

- (1) Only "HCWs who are directly involved in the client's care will have access to the client's records, and only on a 'need-to-know' basis." ⁴⁵
- (2) The records must be stored "in a safe, private and secure place, whether or not they include HIV-related information."
- (3) "[P]ersonal and medical information, including HIV test results, are private and will not be shared without clients' permission."⁴⁷
- (4) Registration numbers need to "be used to identify clients instead of names." (4)
- (5) "Critical information that is not recorded should also be kept strictly confidential."

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5. National Guidelines for the Management of HIV and AIDS

The National Guidelines for the Management of HIV and AIDS ("MHA Guidelines") provide guidance for health facilities and to health care providers who initiate HIV testing and counseling.⁵⁰ The MHA Guidelines include a number of health information security provisions. For a health facility to meet the minimum criteria established under the MHA Guidelines, it must have:

- (1) a confidential consultation room,
- (2) a locked area for medical records with limited access, and
- (3) a proper patient records and reporting system.⁵¹

In addition, the MHA Guidelines note the need to "respect human rights and good clinical practices," which include, among other things, "confidentiality of both the process and the test results" for provider-initiated HIV testing and counseling. ⁵²

6. UNAIDS Privacy Act Guidance

UNAIDS has issued guidance titled Considerations and Guidance for Countries Adopting National Health Identifiers ("UNAIDS Guidance") that includes example elements of a "health data privacy act for individual patients." The UNAIDS Guidance example health data privacy act focuses on restrictions on governmental use of personal health information, but the example act is still a helpful framework for assessing the comprehensiveness of health information privacy laws that apply to public and private actors. This section compares the elements from the UNAIDS Guidance with the provisions of Tanzania's legal and policy health information privacy framework summarized above. ⁵⁴

UNAIDS Example	Explanation	Equivalent Provision in
Privacy Act Element		Tanzanian Law?
1. Definition of personally identifiable information	The UNAIDS Guidance suggests adopting a definition of "personally identifiable information" that includes written, spoken, electronic and all other forms of information about an identifiable individual. 55	Tanzania's HIV and AIDS Act states that "[a]ll health practitioners, workers, employers, recruitment agencies, insurance companies, data recorders, sign language interpreters, legal guardians and other custodians of any medical
		records, files, data or test results shall observe confidentiality in the handling of all medical information and documents." However, the terms "medical records, files, data [and] test results" are not defined in the statute.

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UNAIDS Example	Explanation	Equivalent Provision in
2. Judicial review of privacy violations	The UNAIDS Guidance highlights the importance of judicial review of claims of health information privacy act violations. Specifically, the UNAIDS Guidance notes the importance of judicial review of denial of access to personal health information and improper collection, use, and disclosure of personally identifiable information. ⁵⁷	Tanzanian Law? There is no legal right or specific cause of action under Tanzanian law that allows citizens to bring suit against an information holder for violation of the confidentiality protections of the HIV and AIDS Act.
3. Access and correction rights	The UNAIDS Guidance highlights the importance of patients having the right to access and correct errors in personally identifiable information, regardless of citizenship. ⁵⁸	No.
4. Notice of privacy practices	The UNAIDS Guidance raises the importance of notifying individuals regarding what data may be collected, how it will be used, if the data may be shared, and the consequences of not providing the information. This type of notice is sometimes referred to as a notice of privacy practices. The state of privacy practices of privacy practices.	Tanzanian law does not require providing a notice to patients regarding how their information may be collected, used and/or disclosed. The HIV and AIDS Act lists four exceptions allowing disclosure of medical information: complying with monitoring and evaluation requirements, informing other health practitioners directly involved or about to be involved in treatment or care of a person living with HIV and AIDS, responding to a court order where the main issue is the HIV status of an individual, or giving information to a member of the deceased's family. 61
5. Complaint procedures	The UNAIDS Guidance suggests including in health information privacy acts requirements of providing notice to patients for how to file a complaint in cases of potential misuse of their personally identifiable information. ⁶²	No.

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UNAIDS Example Privacy Act Element	Explanation	Equivalent Provision in Tanzanian Law?
6. Breach notification	The UNAIDS Guidance notes the importance of establishing a duty to notify individuals of an improper use or disclosure of personal health information. ⁶³	No.
7.Limits on data use	The UNAIDS Guidance notes the importance of data only being used for the purposes disclosed and suggests no data matching or aggregation should be allowed without disclosure to the patient. ⁶⁴	The HIV and AIDS Act requires "custodians of any medical records, files, data, or test results" to "observe confidentiality," but does not expressly limit how personal health information can be used by the holder of the information.
8. Least privileged access	The UNAIDS Guidance notes the importance that people who have access to health information systems "are assigned the lowest level of access rights necessary to do their jobs." 65	No.
9. Privacy protections should apply to subcontractors	The UNAIDS Guidance highlights the importance of preserving the confidentiality and accountability of health information that is outsourced to third parties. 66	The HIV and AIDS Act confidentiality provisions apply to "health practitioners, workers, employers, recruitment agencies, insurance companies, data recorders, sign language interpreters, legal guardians and other custodians of any medical records, files, data or test results"
10. Enforcement focal point	The UNAIDS Guidance states that it is important to establish an office of information security or similar government office responsible for implementing the policies and operational mechanisms to support the privacy act. 68	No.

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V. Considerations

The WHO recommends a clear legal framework for the collection, storage, disclosure, and use of health information to protect individual patient data. ⁶⁹ UNAIDS example privacy act includes a number of confidentiality, security and enforcement elements. Some of the elements are addressed by the HIV and AIDS Act or in the policy documents summarized above (HTC SOPs, PMTCT Guidelines, and MHA Guidelines). However, these policies lack the force and effect of law and its associated enforcement mechanisms. To address the elements of the UNAIDS example privacy act, Tanzania could consider adopting a health privacy act that includes UNAIDS' example elements as listed below:

- 1. Clear definition of personally identifiable health information;
- 2. Judicial remedies for privacy violations;
- 3. Access and correction rights;
- 4. Notice of privacy practices;
- 5. Complaint procedures;
- 6. Breach notification requirements;
- 7. Limits on data use;
- 8. Least privileged access;
- 9. Privacy protections apply to subcontractors; and
- 10. Enforcement focal point.

VI. Research Methods

To assess the legal landscape related to confidentiality of health information in Tanzania, the research collaborators searched numerous databases for relevant statutes and articles. Databases searched include, but are not limited to, Lexis-Nexis and the University of Washington WorldCat service (which runs searches across approximately 95 databases worldwide, including PubMed and Academic Search Complete). The search terms used include, but are not limited to, "patient confidentiality in Tanzania," "medical information in Tanzania," "Tanzania and privacy of medical records," and "penalties for breaches of confidentiality in Tanzania." Research limitations included limited access to potentially relevant materials, particularly case law that did not reach the Constitutional or Appellate Courts of Tanzania and materials that were not available in English.

Authors: Jeff Lane, Peter Cooper, Amy Hagopian, Sallie Sanford and Aaron Katz.

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http://www.unaids.org/sites/default/files/media_asset/JC2640_nationalhealthidentifiers_en.pdf. (suggesting that "[a]ll collections of data must enumerate...how an individual files a complaint in cases of potential misuse of their personally identifiable information.").

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c-documents&Itemid=140.

⁶ JESSICA OGDEN & LAURA NYBLADE, COMMON AT ITS CORE: HIV-RELATED STIGMA ACROSS CONTEXTS, 7 (2005), available at http://www.icrw.org/files/publications/Common-at-its-Core-HIV-Related-Stigma-Across-Contexts.pdf (noting that "HIV and AIDS-related stigma and discrimination together have long been recognized as one of the main obstacles to the prevention, care, and treatment of HIV and AIDS.").

⁷ See, e.g., U.S. Department of Health and Human Services, What Are the Specific Privacy and Security Needs of HIV/AIDS Patients? HRSA.GOV,

http://www.hrsa.gov/healthit/toolbox/HIVAIDSCaretoolbox/SecurityAndPrivacyIssues/whatspecifcpriv secneeds.html (last accessed April 23, 2015) (noting that "Patients who are concerned that their health information will not be held private or secure may be discouraged from being tested for HIV and may be dissuaded from pursuing or adhering to recommended treatment regimens.").

⁸ SHARYL NASS, ET AL., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 18 (The National Academies Press ed., 2009).

⁹ USAID, WORKING REPORT MEASURING HIV STIGMA: RESULTS OF A FIELD TEST IN TANZANIA, 3 (2005), available at http://www.icrw.org/files/publications/Working-Report-Measuring-HIV-Stigma-Results-of-a-Field-Test-in-Tanzania.pdf; see also HIV-RELATED STIGMA ACROSS CONTEXTS, supra note 6, at 33–36 (detailing the consequences of stigma for HIV and AIDS treatment and prevention efforts, including its impact on treatment, prevention, and testing).

¹⁰ Chris Beyrer, et al., Expanding the Space: Inclusion of Most-at-Risk Populations in HIV Prevention, Treatment, and Care Services, 57 J. ACQUIR. IMMUNE DEFIC. SYNDR. Supp. 2, S96 (2011), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3164959/pdf/nihms293734.pdf.

² *Id*.

³ *Id.* at 7.

⁴ See, e.g., UNAIDS, CONSIDERATIONS AND GUIDANCE FOR COUNTRIES ADOPTING NATIONAL HEALTH IDENTIFIERS, 51 (2014), available at

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<sup>11</sup> BEYOND THE HIPAA PRIVACY RULE, supra note 8, at 65–66 ("After reviewing the available evidence, the
committee concluded that the public is deeply concerned about the privacy and security of personal health
information, and that the HIPAA Privacy Rule has reduced, but not eliminated, those concerns.").
<sup>12</sup> Id. at 80.
<sup>13</sup> Id.
<sup>14</sup> UNAIDS, DEVELOPING AND USING INDIVIDUAL IDENTIFIERS, note 1, at 3.
<sup>15</sup> WHO, PATIENT MONITORING GUIDELINES FOR HIV CARE AND ANTIRETROVIRAL THERAPY (ART), 9
(2006), available at <a href="http://www.who.int/3by5/capacity/ptmonguidelinesfinalv1.PDF">http://www.who.int/3by5/capacity/ptmonguidelinesfinalv1.PDF</a>.
<sup>16</sup> Id.
<sup>17</sup> Id. at 16.
<sup>18</sup> ADOPTING NATIONAL HEALTH IDENTIFIERS, supra note 4, at 5 (2014).
<sup>19</sup> Id.
<sup>20</sup> Id.
<sup>21</sup> Id. at 6.
<sup>22</sup> Id. at 10.
<sup>23</sup> TANZ. CONST., 1977 as amended, § 16.
<sup>24</sup> HIV & AIDS (Prevention and Control) Act, 2008, § 17(1) (Tanz.).
<sup>25</sup> TANZ. CONST., supra note 23, § 16(1).
<sup>26</sup> Id. § 16(2).
<sup>27</sup> USAID, HEALTH POLICY INITIATIVE IN TANZANIA: END-OF-PROJECT REPORT (2009–2013), 22 (2013),
available at http://pdf.usaid.gov/pdf_docs/pa00jfn7.pdf.
<sup>28</sup> HIV & AIDS Act, supra note 24, § 46.
<sup>29</sup> Id. § 17(1).
<sup>30</sup> Id.
<sup>31</sup> Id. § 18.
<sup>32</sup> Id. § 46
<sup>34</sup> Ministry of Health and Social Welfare, Standard Operating Procedures for HIV Testing and
COUNSELLING (HTC) SERVICES, iv (2009).
<sup>35</sup> Id. at 56.
<sup>36</sup> Id. at 5.
<sup>37</sup> Id.
<sup>39</sup> STANDARD OPERATING PROCEDURES FOR HTC SERVICES, supra note 34, at 5.
<sup>40</sup> Id. at 6.
<sup>41</sup> Id. at 5.
<sup>42</sup> Id. at 6.
<sup>43</sup> MINISTRY OF HEALTH AND SOCIAL WELFARE, NATIONAL GUIDELINES FOR COMPREHENSIVE CARE SERVICES
FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV AND KEEPING MOTHERS ALIVE, 10 (2013),
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44 *Id.* at 26.

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<sup>45</sup> Id.
<sup>46</sup> Id.
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⁴⁷ *Id*.

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⁴⁸ Id.

⁵¹ *Id.* at 22–24.

⁵² *Id.* at 214.

⁵³ ADOPTING NATIONAL HEALTH IDENTIFIERS, *supra* note 4, at 51–52.

⁵⁴ *Id*.

⁵⁵ *Id.* at 51.

⁵⁶ HIV & AIDS Act, *supra* note 24, § 17(1).

⁵⁷ ADOPTING NATIONAL HEALTH IDENTIFIERS, *supra* note 4, at 51.

⁵⁸ Id

⁵⁹ *Id*.

⁶⁰ See, e.g., Notice of Privacy Practices for Protected Health Information, HHS.GOV,

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/notice.html (last accessed August 9, 2015).

⁶¹ HIV & AIDS Act, supra note 24, § 18.

⁶² ADOPTING NATIONAL HEALTH IDENTIFIERS, *supra* note 4, at 51.

63 Id

⁶⁴ *Id.* at 51-52.

⁶⁵ *Id.* at 52.

⁶⁶ Id.

⁶⁷ HIV & AIDS Act, *supra* note 24, § 17(1).

⁶⁸ ADOPTING NATIONAL HEALTH IDENTIFIERS, *supra* note 4, at 52.

⁶⁹ WHO, Management of Patient Information: Trends and Challenges in Member States, 50, 54 (2012), *available at* http://apps.who.int/iris/bitstream/10665/76794/1/9789241504645 eng.pdf.

⁴⁹ NATIONAL GUIDELINES FOR COMPREHENSIVE CARE SERVICES, *supra* note 43, at 26.

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